

1 R. Brent Wisner, Esq. (SBN: 276023)
2 rbwisner@wisnerbaum.com
3 Stephanie B. Sherman, Esq. (SBN: 338390)
4 ssherman@wisnerbaum.com
5 **WISNER BAUM, L.L.P**
6 11111 Santa Monica Boulevard, Suite 1750
7 Los Angeles, CA 90025
8 Telephone: (310) 207-3233
9 Facsimile: (310) 820-7444

10 *Attorneys for Plaintiffs*

11 **UNITED STATES DISTRICT COURT**
12 **CENTRAL DISTRICT OF CALIFORNIA**
13 **WESTERN DIVISION**

14 ALAN MONTENEGRO and MELISSA
15 MEDINA on behalf of themselves, and all
16 others similarly situated, and the general
17 public,

18 Plaintiffs,

19 v.

20 JOHNSON & JOHNSON CONSUMER,
21 INC. and DOES 1 to 50, Inclusive,

22 Defendants.

Civil Action No. 2:24-cv-1895

CLASS ACTION COMPLAINT

**CONSUMER FRAUD, BREACH OF
EXPRESS & IMPLIED
WARRANTIES, AND UNJUST
ENRICHMENT**

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	THE PARTIES	6
III.	JURISDICTION AND VENUE	7
IV.	GENERAL ALLEGATIONS.....	7
A.	JNJ MARKETING ITSELF AS COMMITTED TO SCIENCE AND SAFETY	8
B.	JNJ DID NOT ADEQUATELY TEST THE BPO PRODUCTS BEFORE SELLING THEM TO THE PUBLIC	9
C.	JNJ KNEW OR SHOULD HAVE KNOWN THE BPO PRODUCTS DEGRADED TO BENZENE WHEN EXPOSED TO NORMAL USE, HANDLING, AND STORAGE CONDITIONS.....	10
D.	BENZENE WAS FOUND IN OTHER JNJ PRODUCTS BUT IT DID NOT TEST THE BPO PRODUCTS FOR BENZENE.....	13
E.	JNJ IGNORED FDA’S BENZENE ALERT TO TEST.....	14
F.	RECENT TESTING FOUND COMMON BPO PRODUCTS CONTAIN DANGEROUS LEVELS OF BENZENE IN EXCESS OF REGULATORY LIMITS. 15	
G.	JNJ EXPOSED CONSUMERS TO A RISK OF BENZENE EXPOSURE WITHOUT THEIR KNOWLEDGE.....	20
H.	JNJ DIRECTLY MARKETING THE BPO PRODUCTS TO CHILDREN AND TEENAGERS WITHOUT DISCLOSING THE RISK OF BENZENE CONTAMINATION	23
V.	PUNITIVE DAMAGES ALLEGATIONS.....	24
VI.	PLAINTIFF SPECIFIC ALLEGATIONS.....	25
VII.	CLASS ACTION ALLEGATIONS.....	27
VIII.	CAUSES OF ACTION.....	31
A.	VIOLETION OF CALIFORNIA’S UNFAIR COMPETITION LAW BUS. & PROF. CODE § 17200 <i>et seq.</i> , Individually and on Behalf of the California Subclass	31
B.	VIOLETION OF CALIFORNIA’S CONSUMER LEGAL REMEDIES ACT, Cal. Civ. Code § 1750, <i>et seq.</i> , Individually and on Behalf of the California Subclass	33
C.	FALSE ADVERTISING UNDER VARIOUS STATE STATUTES, Individually and on Behalf of the California, Hawaii, and New York Subclasses.....	36

D.	DECEPTIVE TRADE PRACTICES UNDER VARIOUS STATE STATUTES, Individually and on Behalf of California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses	39
E.	BREACH OF EXPRESS WARRANTY, Individually and on Behalf of the Nationwide Class and on Behalf of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses	43
F.	BREACH OF IMPLIED WARRANTY, Individually and on Behalf of the Nationwide Class and on Behalf of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses	44
G.	UNJUST ENRICHMENT, Individually and on Behalf of the Nationwide Class and on Behalf of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses.....	46
IX.	PRAYER FOR RELIEF	47
X.	DEMAND FOR JURY TRIAL	47

1 Plaintiffs, ALAN MONTENEGRO, and MELISSA MEDINA on behalf of
 2 themselves, the proposed Class, and Subclasses (defined below), and the public, brings
 3 this Class Action Complaint (“Class Action”) against Defendant, alleging the following
 4 upon Plaintiffs’ personal knowledge, or where Plaintiffs lack personal knowledge, upon
 5 information and belief, including the investigation of counsel.

6 I. INTRODUCTION

7 1. This is a consumer fraud Class Action to redress the economic harms
 8 caused by Defendant’s sale of benzoyl peroxide acne treatment drug products (“BPO
 9 Products” or “Products”) without warning consumers the BPO Products had unsafe
 10 levels of the potent human carcinogen benzene, and that the BPO Products were at risk
 11 of degrading further into benzene under normal use, handling, and storage conditions.

12 2. The BPO Products are “drugs” used to treat acne vulgaris (“acne”),
 13 formulated with a chemical called benzoyl peroxide (“BPO”), along with other inactive
 14 ingredients, to make acne treatment creams, washes, scrubs, and bars. Before being
 15 sold to the public, the Products must be made in conformity with current good
 16 manufacturing practices and must conform to quality, safety, and purity specifications.
 17 Defendant’s BPO Products did not.

18 3. BPO Products should not have benzene, nor degrade into benzene, except
 19 under extraordinary circumstances.¹ A drug is “adulterated” if it consists in whole or in
 20 part of any filthy, putrid, or decomposed substance, is impure, or mixed with another
 21 substance.² Under the Federal Food, Drug and Cosmetic Act, it is a crime to introduce
 22 or deliver “into interstate commerce any food, drug, device, tobacco product, or
 23 cosmetic that is adulterated or misbranded.”³ If benzene is found in any on-market or
 24
 25

26 ¹ Food and Drug Administration, *Q3C – Tables and List Guidance for Industry* (2017),
 27 <https://www.fda.gov/media/71737/download>.

28 ² 21 U.S.C. § 351(a)(2011); *see also* § 351(b)-(d) (noting that a lack of purity or mixture with another substance also renders drug adulterated).

³ 21 U.S.C. § 331(a)(2011).

1 post-market Product, the drug is adulterated, unlawful and the drug manufacturer must
2 contact the Food and Drug Administration (“FDA”) initiate a voluntary recall.⁴

3 4. Throughout this Complaint, references to federal law and FDA regulation
4 are merely to provide context and are not intended to raise a federal question of law.
5 All claims alleged herein arise out of violations of state law, which in no way conflict,
6 interfere with, or impose obligations that are materially different than those imposed by
7 federal law.

8 5. The BPO Products marketed and sold by Defendant to Plaintiffs, the
9 putative Class members, and the public decomposed into benzene rendering them
10 materially different than advertised, *i.e.*, by containing unsafe levels of benzene.
11 Benzene is a known human carcinogen. Studies dating to the 1800s have led to a
12 consensus within the medical and scientific communities that benzene exposure, even
13 in low amounts, increases the risk of blood cancers and other adverse effects.

14 6. In 2023, Valisure, LLC,⁵ an independent, accredited laboratory that has
15 developed analytical methods to test drugs and consumer products for public safety,
16 tested a representative sample of BPO and non-BPO products and found the BPO
17 Products had dangerous levels of benzene, many multiple times higher than allowed in
18

19 ⁴ Food and Drug Administration. (Dec. 22, 2022). *FDA Alerts Drug Manufacturers to the Risk of Benzene in*
20 *Certain Drugs*, [https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-](https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs)
21 [risk-benzene-contamination-certain drugs](https://www.fda.gov/drugs/pharmaceutical-quality-resources/fda-alerts-drug-manufacturers-risk-benzene-contamination-certain-drugs) (last visited Feb. 9, 2024).

22 ⁵ Valisure is an independent third-party analytical laboratory that is accredited to International Organization for
23 Standardization (“ISO/IEC”) 17025:2017 standards for chemical testing (PJLA Accreditation Number 94238).
24 In response to rising concerns about drug shortages, generics, and overseas manufacturing, Valisure developed
25 and validated methods to test medications and consumer products distributed in the United States. Valisure has
26 tested a variety of drug and consumer healthcare products for benzene including sunscreens, antiperspirants,
27 body sprays, hand sanitizers, and dry shampoos for benzene. Valisure’s testing results submitted to the FDA in
28 its Citizen’s Petitions, were widely publicized in the media leading to numerous recalls of contaminated
consumer products. *See* Valisure Citizen’s Petition on Benzoyl Peroxide (March 4, 2024), pp. 6-7, *see also*
Valisure Detects Benzene in Sunscreen, [https://www.valisure.com/valisure-newsroom/valisure-detects-](https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-sunscreen)
benzene-in-sunscreen; Bruce Y. Lee, Forbes, FDA: P&G Recalls Antiperspirant Sprays Due To Cancer Risk Of
Benzene (Nov. 24, 2021), [https://www.forbes.com/sites/brucelee/2021/11/24/fda-pg-recalls-antiperspirants-](https://www.forbes.com/sites/brucelee/2021/11/24/fda-pg-recalls-antiperspirants-body-sprays-due-to-cancer-risk-of-benzene/?sh=69cf13c24f32)
body-sprays-due-to-cancer-risk-of-benzene/?sh=69cf13c24f32; *see also* Sandee LaMotte, CNN, Antiperspirant
recall: What the finding of a cancer-causing chemical means for you (Dec. 1, 2021),
[https://www.cnn.com/2021/12/01/health/deodorants-antiperspirants-recall-benzene-explainer-](https://www.cnn.com/2021/12/01/health/deodorants-antiperspirants-recall-benzene-explainer-wellness/index.html)
wellness/index.html.

any regulated drug.⁶ Using industry standard gas chromatography and detection by mass spectrometry (“GC-MS”) instrumentation, with selected ion flow tube mass spectrometry (“SIFT-MS”) for detection of benzene released into the air around certain BPO Products, the Products were incubated to temperatures common during consumer use, handling, and storage and sampled for benzene.⁷ Levels as high as 1600 parts per million (ppm) were found in Defendant’s Product, 2.5% Cream.⁸ Unexpectedly, researchers found that benzene was released into the surrounding air outside the Products’ containers even when the packaging and containers were closed raising concern for even more inhalation exposures—a particularly pernicious form of exposure to benzene.⁹ For the non-BPO products tested, benzene was not present, or at trace levels below 2 ppm.¹⁰ Valisure filed a FDA Citizen’s Petition on March 5, 2024 demanding an immediate recall of all BPO Products.¹¹ The Petition is pending.¹²

7. The high levels of benzene found led Valisure to conduct a stability study on a diverse market sweep of BPO Products and formulations. Valisure’s results show that on-market BPO Products can form over 800 times the conditionally restricted FDA concentration limit of 2 ppm for benzene, and the evidence suggests this problem applies broadly to BPO Products currently on the market.¹³ Valisure concluded that on-market BPO Products appear to be fundamentally unstable and form unacceptably high

⁶ Valisure FDA Citizen’s Petition on Benzoyl Peroxide (March 6, 2024).

⁷ *Id.*

⁸ *Id.* at 17.

⁹ *Id.* at 23.

¹⁰ *Id.* at 15 (“76 non-BPO products had no detectable benzene or values below 0.1ppm. 6 non-BPO products contained traces of benzene below 2 ppm, which could be due to various inactive ingredients used in consumer products that have been theorized to contain trace benzene”); *see also* Valisure, LLC, <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide> (last visited March 6, 2024).

¹¹ Valisure’s Citizen Petition on Benzene in Benzoyl Peroxide Products (March 5, 2024), *available at*: <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide> (last visited March 7, 2024).

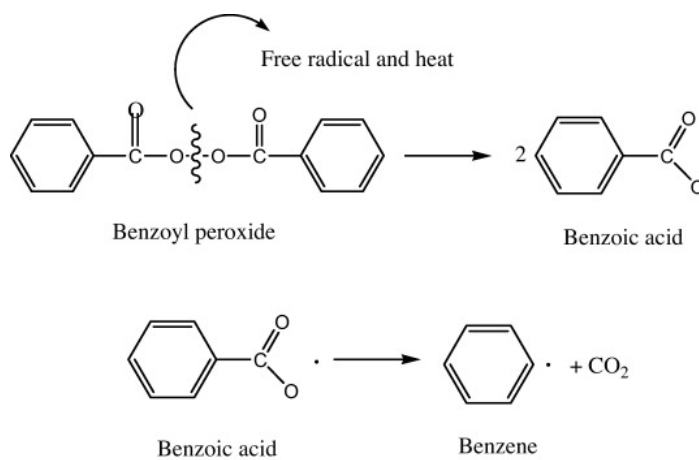
¹² Valisure’s Citizen’s Petition was still pending as of this Class Action’s filing.

¹³ Valisure, LLC, (March 6, 2024), *Valisure Discovers Benzoyl Acne Treatment Products are Unstable and Form Benzene*, <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide> (last visited March 6, 2024).

1 levels of benzene when handled or stored at temperatures the Products will be exposed
2 to during expected use and handling by consumers.¹⁴

3 8. Although the BPO Products have been found to have benzene, Defendant
4 never listed benzene among its Products' ingredients, or anywhere on the Products'
5 labels, containers, advertising or on Defendant's websites. Defendant never warned
6 anyone the Products had benzene or were at risk of benzene contamination.

7 9. Defendant knew or should have known its BPO Products contain and/or
8 degraded into benzene when exposed to expected consumer use, handling, and storage
9 conditions. BPO is known, within the scientific community (but not among consumers)
10 to degrade into benzene according to the mechanism below:¹⁵



20 10. Defendant misled the Plaintiffs, the putative California members, and the
21 public by representing its BPO Products only had the ingredients listed on the labels,
22 packaging, containers, and on its website. Defendant misled the Plaintiffs, the putative
23 Class members, and the public by representing the BPO Products were safe while

24 _____
25 ¹⁴ *Id.*

26 ¹⁵ The disposition of benzoyl peroxide to form benzene. Benzoyl peroxide is known to thermally decompose to
27 form two molecules of benzoyloxy radicals that can further decompose to benzoic acid or phenyl radicals with
28 liberation of carbon dioxide. The phenyl radicals can then produce benzene. See Shang-Hao Liu, et al,
Thermal hazard evaluation of the autocatalytic reaction of benzoyl peroxide using DSC and TAM III,
THERMOCHIMICA ACTA, Volume 605, Pages 68-76, , (2015), ISSN 0040-603,
<https://www.sciencedirect.com/science/article/pii/S004060311500057X>.

1 concealing material health and safety information known to them, *e.g.*, that the BPO
2 Products degraded to benzene, or were contaminated with benzene. Defendant misled
3 Plaintiff, the putative Class members, and the public by giving the BPO Products long
4 expiration dates of 2-3 years, leading consumers to believe the Products were safe for
5 use for years when Defendant knew or should have known the Products degraded into
6 benzene much sooner and were likely already contaminated by the time the Products
7 were first used by the consumer.

8 11. Defendant's statements and omissions of material health and safety
9 information are prohibited deceptive trade practices and false and deceptive
10 advertising. Defendant's statements about the Products were false, misleading,
11 unsubstantiated, untruthful, and blatantly deceptive. Even more egregious is Defendant
12 unreasonably placed Plaintiffs, the putative Class members, and the public at risk of
13 exposure to benzene, and at increased risk of cancer, without their knowledge and
14 consent.

15 12. Because of the Defendant's misconduct and consumer deception, the
16 Plaintiffs and the putative Class members were economically harmed, as they bought
17 Products they otherwise would have never bought. They were also physically harmed
18 by being exposed to a known human carcinogen.

19 13. This Class Action is necessary to redress the economic harms caused to the
20 Plaintiffs and the putative Class members who bought the Products believing them to
21 be safe. This Class Action is further necessary to expose Defendant's ongoing
22 consumer fraud and to enjoin Defendant from continuing its misconduct to protect
23 consumers and the public.

24 14. Plaintiffs bring this Class Action individually, and on behalf of those
25 similarly situated, and seek to represent a National Class of consumers and State
26 Subclasses of consumers (defined *infra*) who bought the Products. Plaintiffs seek
27 damages, reasonable attorneys' fees and costs, interest, restitution, and all other
28

1 equitable relief, including an injunction and disgorgement of all benefits and profits
2 Defendant received from its misconduct.

3 **II. THE PARTIES**

4 15. Plaintiff Alan Montenegro is a California resident, located in Los Angeles
5 County who bought BPO Products including Neutrogena Rapid Clear Stubborn Acne
6 Spot Gel from 2017 to 2021. Plaintiff has suffered economic damages and a result of
7 Defendant's violations of the state laws alleged herein. Plaintiff would never have
8 purchased Defendant's BPO Products had Defendant warned about the presence of
9 benzene or that the Products could degrade into benzene.

10 16. Plaintiff Melissa Medina is a Nevada resident, located in Carson County
11 who bought BPO Products including Clean & Clear Continuous Control Acne Cleanser
12 from September 2020 to May 2023. Plaintiff has suffered economic damages and a
13 result of Defendant's violations of the state laws alleged herein. Plaintiff would never
14 have purchased Defendant's BPO Products had Defendant warned about the presence
15 of benzene or that the Products could degrade into benzene.

16 17. Defendant Johnson & Johnson Consumer Inc. is a citizen of New Jersey
17 and Delaware, with its principal place of business located at 199 Grandview Road,
18 Skillman, New Jersey 08558. Johnson & Johnson Consumer Inc. is a subsidiary of
19 Johnson & Johnson (JNJ) who sells BPO Products under the brand names Clean and
20 Clear and Neutrogena. JNJ's Products include, inter alia: (1) Persa-Gel® 10, (2) Clean
21 & Clear Continuous Control Benzoyl Peroxide Acne Face Wash, (3) Neutrogena Rapid
22 Clear Stubborn Acne Spot Gel, (4) Neutrogena On the Spot Acne Treatment, (5)
23 Neutrogena Stubborn Acne AM Treatment, and (6) Stubborn Marks PM Treatment. At
24 all relevant times, JNJ conducted business and derived substantial revenue from its
25 manufacturing, advertising, marketing, distributing, and selling of the Products within
26 the State of California.

27 18. Defendant and its agents promoted, marketed, and sold the Products in
28 California and in this District. The unfair, unlawful, deceptive, and misleading

1 advertising and labeling of the Products were prepared and/or approved by Defendant
2 and its agents and were disseminated by Defendant and its agents through statements,
3 labeling and advertising containing the misrepresentations alleged and disseminated
4 uniformly through advertising, packaging, containers, and via websites and social
5 media.

6 **III. JURISDICTION AND VENUE**

7 19. This Court has jurisdiction over this matter because the amount in
8 controversy exceeds \$5 million satisfying 28 U.S.C. § 1332(d)(2) for subject matter
9 jurisdiction. This Court has supplemental jurisdiction over any state law claims under
10 28 U.S.C. § 1367.

11 20. Venue is proper in the Central District of California under 28 U.S.C. §
12 1391(b) because a substantial part of the events or omissions giving rise to the claims
13 occurred in this District.

14 21. This Court has personal jurisdiction over the Defendant because Defendant
15 transacts business in California, including in this District, has substantial aggregate
16 contacts with the State of California, including in this District, engaged in misconduct
17 that has and had a direct, substantial, reasonably foreseeable, and intended effect of
18 injuring people in this District, and Defendant purposely availed itself of the benefits of
19 doing business in the State of California, and in this District. Additionally, the claims
20 by Plaintiffs arise out of and relate to the Defendant's action within the State of
21 California and in this District.

22 22. To the extent applicable, the Court also has pendant personal jurisdiction
23 over claims alleged against Defendant that involve the same common nucleus of facts
24 and actions that give rise to Plaintiffs' claims that otherwise have proper personal
25 jurisdiction within this Court.

26 **IV. GENERAL ALLEGATIONS**

27 23. Fifty million Americans suffer from acne annually.¹⁶ Acne is the most
28

¹⁶ American Association of Dermatology, <https://www.aad.org/media> (visited October 24, 2023).

1 common skin condition in the United States with a prevalence among adolescents of
 2 almost 95 percent.¹⁷ Acne can begin as early as age seven and, for some, can persist
 3 through adulthood and into ages 50s and 60s.¹⁸ Millions of acne sufferers seek
 4 treatment every year making it a billion-dollar industry and a key business segment for
 5 Defendant, who are among America's most prominent companies.

6 **A. JNJ MARKETED ITSELF AS COMMITTED TO SCIENCE AND**
 7 **SAFETY**

8 24. Defendant JNJ's most profitable and well-known acne treatment products
 9 contain BPO. To make the finished BPO Products, BPO, a dry white powder, is mixed
 10 with other ingredients to create topical drug creams, cleansers, scrubs, and washes for
 11 use on the face and body. BPO is formulated into these Products at concentrations up to
 12 10%.

13 25. Defendant JNJ is a household name familiar to every American. JNJ
 14 started over 135 years ago and employs over 150,000 employees around the globe. In
 15 2022, JNJ's annual revenue was 94.9 billion dollars. JNJ markets itself as a world
 16 leader in pharmaceutical and consumer healthcare innovation and research. In 2022,
 17 JNJ spent \$14.6 billion on research and development. JNJ's business falls into three
 18 areas - pharmaceuticals, consumer health, and medtech. JNJ's BPO Products, i.e.,
 19 Clean & Clear and Neutrogena, fall under the consumer health umbrella that includes
 20 other widely used personal healthcare products such as Band-Aid, Neosporin, Tylenol,
 21 Motrin, Sudafed, Benadryl and Zyrtec allergy products and Johnson's and Aveeno baby
 22 care line of products. JNJ's Products are marketed and sold online to retail outlets and
 23 distributors throughout the world.

24 26. JNJ marketed itself as a world class pharmaceutical and consumer health
 25 care product researcher, developer, and seller who devoted substantial resources to
 26 product development. Indeed, JNJ reported that it spent \$14.6 billion on research and
 27

28 ¹⁷ JL Burton et al., *The prevalence of acne vulgaris in adolescence*, BR J DERMATOL,(1971);85(2):119–126.

¹⁸ *Id.*

1 development in 2023.¹⁹

2 27. JNJ marketed itself as a company committed to safety and science. JNJ
3 told consumers: “we are driven by a responsibility to create science-backed skin care
4 that everyone can access.”²⁰ On JNJ’s website for Neutrogena®, JNJ said they “set a
5 high bar for using ingredients...screening for quality, manufacturing process,
6 government regulations, published and research...”²¹ JNJ assured consumers, BPO is
7 the number one dermatologist approved over the counter acne ingredient.²²

8 28. Defendant’s broad claims of safety gave consumers a false sense of safety.
9 Defendant’s statements were meant to convey the BPO Products were safe and did not
10 contain carcinogens such as benzene. Defendant made these statements uniformly to
11 the public and through its websites, Product labels, containers, and advertising.

12 **B. JNJ DID NOT ADEQUATELY TEST THE BPO PRODUCTS**
13 **BEFORE SELLING THEM TO THE PUBLIC**

14 29. Despite Defendant’s public affirmations of its commitment to science,
15 Defendant did not adequately test its BPO Products before selling them to consumers.
16 Defendant’s Products are “drugs” regulated by the FDA. As with any regulated drug,
17 Defendant must follow current good manufacturing practices (“CGMPs”), have
18 scientifically sound specifications, and must have test procedures and processes to
19 ensure the drug’s components (active and inactive ingredients), and finished products
20 are safe. Both raw ingredient materials and finished batches must be tested before
21 released to the public to confirm they meet specifications for identity, strength, quality,
22 and purity.²³ If testing results of the raw materials or finished product do not conform
23 with the specifications, the product cannot be sold to the public. Defendant must also

24 _____
25 ¹⁹ Johnson & Johnson (Oct. 23, 2023). *Form 10-K 2023*. Retrieved from SEC EDGAR website
<http://www.sec.gov/edgar.shtm>.

26 ²⁰ Why Neutrogena? Retrieved from: <https://www.neutrogena.com/why-neutrogena.html> accessed October 7,
2023).

27 ²¹ Neutrogena, Product Testing. Retrieved from: <https://www.neutrogena.com/producttesting.html> (last
28 accessed October 7, 2023).

²² See Neutrogena Stubborn Acne AM Treatment container.

²³ 21 C.F.R. § 211.84 (1978); *see also* 21 C.F.R. § 211.160 (1978).

1 re-test any Products subject to deterioration.²⁴ Any Products not made in conformity
 2 with the CMGPs is considered “adulterated” under 501(a)(2)(B) of the Food, Drug, and
 3 Cosmetic Act.²⁵

4 30. Defendant must also do stability testing to understand the “shelf life” of the
 5 Products and to assign an expiration date. It is well known that certain chemical
 6 ingredients can degrade or change because of environmental, and storage conditions
 7 such as light, moisture, temperature, and humidity, or because of the passage of time.
 8 The stability testing should cover all expected distributor and consumer storage,
 9 handling, and use conditions and must be done using “reliable, meaningful, and specific
 10 test methods.”²⁶ If stability testing finds a drug product is not stable under expected
 11 storage or use conditions, degrades, or create toxic byproducts, the product cannot be
 12 sold to the public.

13 31. The CGMPs and stability test requirements are there to ensure drug
 14 products are safe for public use. These are the minimum requirements. Because the
 15 drug manufacturers are largely self-regulated, the FDA must rely on drug
 16 manufacturers, the public, and concerned citizens to report unsafe drugs. The FDA
 17 cannot force a drug manufacturer to recall a contaminated drug.²⁷

18 **C. JNJ KNEW OR SHOULD HAVE KNOWN THE BPO PRODUCTS**
 19 **DEGRADED TO BENZENE WHEN EXPOSED TO NORMAL USE,**
 20 **HANDLING, AND STORAGE CONDITIONS**

21 32. Defendant knew or should have known the BPO Products degraded to
 22 benzene when exposed to normal use, handling, and storage conditions. Defendant

23 ²⁴ 21 C.F.R. § 211.160(b)(1)(1978).

24 ²⁵ 21 C.F.R. § 225.1 (1976). Under 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act a drug is
 25 considered “adulterated” (poorer in quality by adding another substance) if the methods used in, or the facilities
 26 or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or
 administered in conformity with CGMP; *see also* Food and Drug Administration, *Facts About the Current*
Good Manufacturing Practices (CGMP); <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmp> (last visited Feb. 11, 2024).

27 ²⁶ 21 CFR 211.166.

28 ²⁷ Food and Drug Administration, *Facts About the Current Good Manufacturing Practices (CGMP)*;
<https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmp> (last visited Feb. 11, 2024).

1 knew that, because of the chemical nature of the active and inactive ingredients,
 2 including BPO, the BPO Products were not stable and would degrade when exposed to
 3 heat from normal distributor and consumer use, handling, and storage conditions.

4 33. It is well known that BPO degrades to benzene when exposed to heat over
 5 time. This process was first reported in the scientific literature as early as 1936.²⁸

6 34. The degradation of BPO to benzene was known or should have been
 7 known to the Defendant, who promoted themselves as devoting substantial money and
 8 resources to science and research. Defendant marketed themselves as world class drug
 9 and healthcare researchers, developers, and sellers. Defendant employed high-level
 10 scientists, chemists, and researchers to formulate its drug products for public use.
 11 Defendant had one of the most recognized acne brand Product and the financial gains
 12 by such recognition. Defendant of these resources and expertise were aware of the well-
 13 known chemical processes that degrade its BPO Products into benzene when exposed
 14 to common use temperatures and conditions.

15 35. Defendant further knew or should have known that specific ingredients
 16 derived from hydrocarbons increased the risk the BPO Products would yield benzene.²⁹
 17 At-risk ingredients include carbomers, mineral spirits, and other petroleum derived
 18 substances. These ingredients are red flags for risk of benzene contamination. The FDA
 19 published guidance in 2022 urging the industry to reformulate drug products at risk of
 20 benzene contamination.³⁰ The FDA's alert highlighted ingredients made from
 21 hydrocarbons, including carbomers (thickening agents), urging drug manufacturers to
 22 test products containing them for benzene contamination.³¹ Many of the Defendant's
 23

24 ²⁸ H. Erlenmeyer and W. Schoenauer, *Über die thermische Zersetzung von Di-acyl-peroxyden*, HELV. CHIM.
 25 ACTA, 19, 338 (1936), <https://onlinelibrary.wiley.com/doi/10.1002/hlca.19360190153> (last visited Feb. 5,
 26 2024).

27 ²⁹ Food and Drug Administration. (Dec. 22, 2022). *FDA Alerts Drug Manufacturers to the Risk of Benzene in*
 28 *Certain Drugs*.

³⁰ Food and Drug Administration. *Reformulating Drug Products That Contain Carbomers*
Manufactured With Benzene (December 27, 2023), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reformulating-drug-products-contain-carbomers-manufactured-benzene>.

³¹ *Id.*; see also December 22, 2022 FDA Alert at 1.

1 Products contain hydrocarbons and carbomers but none have been recalled due to
2 benzene contamination.

3 36. Defendant knew or should have known through its own research,
4 development, formulation, manufacturing, and testing whether the BPO Products were
5 chemically and physically stable. Defendant were required not only to adequately test
6 the BPO Products for safety and stability before selling them to the public, but also to
7 monitor internal practices, processes, and specifications to make sure they kept pace
8 with science and emerging methodologies. Defendant knew or should have known
9 from expiration and stability studies examining the “shelf life” of the BPO Products,
10 the chemical changes took place because of normal and expected environmental, use,
11 and storage conditions.

12 37. Defendant knew or should have known the BPO Products would be
13 handled, used, and stored by distributors, sellers, and consumers under various
14 temperatures that affect chemical stability. Defendant knew or should have known the
15 BPO Products would travel by commercial carriers and distributors in varying storage
16 conditions and would be stored by consumers in handbags, backpacks, bathrooms,
17 showers, lockers, and in vehicles during warm months where the BPO Products would
18 be exposed to heat. Defendant knew or should have known consumers would apply the
19 benzene contaminated BPO Products to their faces and bodies and would also use the
20 BPO Products in heated showers as scrubs and washes. Defendant knew or should have
21 known the BPO Products would be used and applied to the skin at normal body
22 temperatures, and elevated temperatures following showers or baths, after physical
23 activity, and after the BPO Products sat in warm temperatures or hot vehicles.

24 38. These storage, use, and handling conditions were known or should have
25 been known to Defendant before the BPO Products were marketed and sold to
26 Plaintiffs, the Class, and Subclass members. Defendant knew or should have known the
27 BPO Products degrade to benzene under these conditions exposing consumers to
28 benzene. Defendant further knew or should have known that, because of the known

1 degradation of BPO to benzene, its BPO Products were contaminated with benzene by
 2 the time they reached consumers, but they sold them to Plaintiffs, the Class, the
 3 Subclass, and the public anyway, without warning of the risk of exposure. Moreover,
 4 the 2–3-year shelf life printed on the BPO Products told consumers they were safe for
 5 use for years, when they were not.

6 **D. BENZENE WAS FOUND IN OTHER JNJ PRODUCTS BUT IT DID**
 7 **NOT TEST THE BPO PRODUCTS FOR BENZENE**

8 39. In 2020, the FDA started working with companies to identify benzene in
 9 products, which resulted in product recalls of hand sanitizers, sunscreens, and
 10 deodorants. In 2021, an independent chemical analysis by Valisure of hundreds of
 11 sunscreens and after-sun care products from 69 brands found 27 percent of the batches
 12 had significant levels of benzene above the FDA 2 ppm limit.³² JNJ’s Aveeno and
 13 Neutrogena sunscreen lines were among the most benzene contaminated and were
 14 recalled.³³ CVS’s private brand after-sun care products were also highly contaminated
 15 with benzene, but not recalled by CVS. By 2021, Defendant was aware of benzene
 16 contamination issues in its own consumer products but continued to advertise and sell
 17 the BPO Products without testing them for benzene.

18 40. Defendant JNJ’s lack of transparency around carcinogens in its products
 19 goes back even further. JNJ has been sued by tens of thousands of ovarian cancer
 20 victims due to JNJ’s concealment of asbestos in talcum powder. JNJ internal
 21 documents show JNJ was aware since the late 1950s the talc used in Johnson’s Baby
 22 Powder sometimes contained asbestos, known to cause health issues including cancer
 23 and mesothelioma. Instead of warning consumers about possible health risks, JNJ
 24 doubled down on aggressively marketing its talc-based baby powder to women who
 25 used the talc on themselves and their babies. An internal JNJ memo from 1992
 26

27 ³² See Valisure Citizen Petition on Benzene in Sunscreen and After-sun Care Products, May 24, 2021.

28 ³³ Press Release. (July 14, 2021), Johnson & Johnson Consumer Inc. Johnson & Johnson Consumer Inc.
Voluntarily Rec of Specific Neutrogena and Aveeno Aerosol Sunscreen Products Due to the Presence of Benzene.

1 acknowledged the potential links to cancer, while simultaneously recommending
 2 increased marketing to African American and Hispanic women. JNJ handled out free
 3 samples in black communities and started radio ads on Hispanic stations.

4 41. JNJ owns the lion's share of the BPO acne treatment market with several
 5 products under brand names Neutrogena, PersaGel, and Clean & Clear.

6 **E. JNJ IGNORED FDA'S BENZENE ALERT TO TEST**

7 42. In 2022, the FDA issued a safety alert warning drug manufacturers of the
 8 risk of benzene contamination in certain drug products and drug components. The FDA
 9 reiterated the risk benzene exposure poses to public health and the drug manufacturers'
 10 obligations to test drug products under the U.S. Code of Federal Regulations, Title 21.

11 43. The FDA reminded drug manufacturers they were required to establish
 12 scientifically sound and appropriate specifications and test procedures to assure drug
 13 components (active and inactive ingredients) and finished drug products conform to
 14 appropriate quality specifications (21 C.F.R. 211.84, 21 C.F.R. 211.160). This included
 15 testing of raw materials and finished batches (21 C.F.R. 211.165) prior to release to
 16 ensure they met appropriate specifications for identity, strength, quality, and purity.³⁴

17 44. The FDA warned drug manufacturers that any drug products or
 18 components at risk of benzene contamination should be tested, and any batches with
 19 benzene above 2 ppm should not be released to the public.³⁵ The FDA further warned
 20 that, if any drug or drug component was subject to deterioration, drug manufacturers
 21 must have re-testing procedures in place to ensure continued purity and stability. If any
 22 drug product in circulation was found to have benzene over 2ppm, the FDA directed
 23 that drug manufacturers contact the FDA to discuss a voluntarily recall.³⁶

24 45. To date, none of the Defendant's Products have been recalled due to
 25 benzene contamination, and none have voluntarily notified consumers of contamination
 26

27 ³⁴ Federal Drug Administration. (Dec. 22, 2022). *FDA Alerts Drug Manufacturers to the Risk of Benzene in*
Certain Drugs, 1.

28 ³⁵ *Id.*, 3.

³⁶ *Id.*, 2.

1 or risk of contamination.

2 **F. RECENT TESTING FOUND COMMON BPO PRODUCTS**
 3 **CONTAIN DANGEROUS LEVELS OF BENZENE IN EXCESS OF**
 4 **REGULATORY LIMITS**

5 46. Testing by Valisure in 2023 found common acne treatment products
 6 formulated with BPO are not only contaminated with benzene but have levels
 7 dangerous to public health. Valisure is an accredited independent laboratory who has
 8 developed validated analytical methods³⁷ to test drugs and consumer products to
 9 address rising concerns about public safety. Valisure has tested a wide variety of drugs
 10 and products for benzene including sunscreens, antiperspirants, hand sanitizers, and dry
 11 shampoos. Their work has led to widely publicized product recalls protecting the public
 12 from dangerous and carcinogenic consumer products.³⁸

13 47. In 2023, Valisure tested 175 finished acne treatment products to determine
 14 whether any had benzene. Of the 175 products tested, 99 were formulated with BPO,
 15 58 had active ingredients (either individually or in combination) of salicylic acid,
 16 sulfur, adapalene, azelaic acid, niacinamide and zinc, and 18 had no drug ingredients.³⁹

17 ³⁷ Valisure's test methods largely mirror those utilized by FDA's own "Drug Quality Sampling and Testing"
 18 ("DQST") Program. Valisure FDA Citizen's Petition at 4.

19 ³⁸ See Valisure May 24, 2021 Citizen Petition on Benzene in Sunscreen and After-sun Care Products,
 20 <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-sunscreen>; Valisure's Citizen
 21 Petition on Hand Sanitizer Products Containing Benzene Contamination (filed March 24, 2021),
 22 <https://www.regulations.gov/document/FDA-2021-P-0338-0001>, Valisure's Citizen Petition on Benzene in
 23 Sunscreen and After-sun Care Products (filed May 24, 2021), <https://www.regulations.gov/document/FDA-2021-P-0497-0001>, Valisure's Citizen Petition on Benzene in Body Spray Products (filed November 3, 2021),
 24 <https://www.regulations.gov/document/FDA-2021-P-1193-0001>, Valisure's Citizen Petition on Benzene in
 25 Dry Shampoo Products (filed October 31, 2022), <https://www.regulations.gov/document/FDA-2022-P-2707-0001> see also CNET, Dry Shampoo Recall: What Is Benzene and Which Brands Are Affected
 26 <https://www.cnet.com/health/personal-care/dry-shampoo-recall-what-is-benzene-and-which-brands-are-affected/> (identifying 19 types of dry shampoo have been recalled due to benzene content); Ryan Basen,
 27 Medpage Today, After Valisure Petition, Ol' Dirty Benzene Forces Another Recall (November 30, 2021),
 28 <https://www.medpagetoday.com/special-reports/exclusives/95929> ("After Valisure Petition, Ol' Dirty Benzene Forces Another Recall"); Bruce Y. Lee, Forbes, FDA: P&G Recalls Antiperspirant Sprays Due To Cancer Risk Of Benzene (Nov. 24, 2021), <https://www.forbes.com/sites/brucelee/2021/11/24/fda-pg-recalls-antiperspirants-body-sprays-due-to-cancer-risk-of-benzene/?sh=69cf13c24f32>; see also Sandee LaMotte, CNN, Antiperspirant recall: What the finding of a cancer-causing chemical means for you (Dec. 1, 2021), <https://www.cnn.com/2021/12/01/health/deodorants-antiperspirants-recall-benzene-explainer-wellness/index.html>.

³⁹ See Valisure Citizen's Petition on Benzoyl Peroxide (March 4, 2024).

83 of the BPO Products were purchased over the counter from major retailers and 16 were prescription products purchased from licensed wholesalers.⁴⁰ The BPO Products included popular Products: Proactiv 2.5% BPO Cream, Target Up & Up 2.5% BPO Cream, Equate Beauty 10% BPO Cream, Equate BPO Cleanser, Neutrogena 10% BPO Cleanser, Clearasil 10% BPO Cream, CVS Health 10% BPO Face Wash, Walgreens 10% BPO Cream, La Roche Posay BPO Cream, and Clean & Clear 10% BPO Lotion.

48. Valisure used three incubation temperatures to evaluate the effects of common distributor and consumer use, handling, and storage conditions on benzene formation. 37°C/98.6°F was used for human body temperature, 50°C/122°F was used to evaluate shelf-life performance as an accelerated stability testing temperature used by the pharmaceutical industry,⁴¹ and 70°C/158°F to model storage in a hot vehicle.⁴² The BPO Products were incubated at 37°C for four weeks and 50°C for three weeks and benzene concentration was measured at certain time intervals using GC-MS. Benzene findings were plotted in real time and reported in parts per million (“ppm”). The results below were submitted to the FDA in Valisure’s March 5, 2024 Citizen’s Petition on Benzoyl Peroxide.⁴³

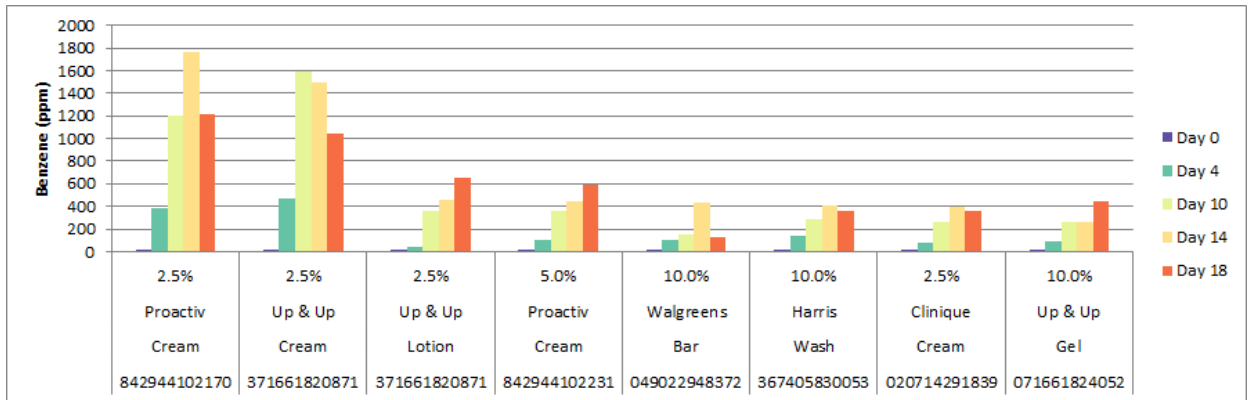
⁴⁰ *Id.*

⁴¹ Ghimire, Prakash et al., *Guidelines on Stability Studies of Pharmaceutical Products and Shelf Life Estimation*. INTERNATIONAL JOURNAL OF ADVANCES IN PHARMACY AND BIOTECHNOLOGY, (2020). 06. 15-23. 10.38111/ijapb.20200601004.

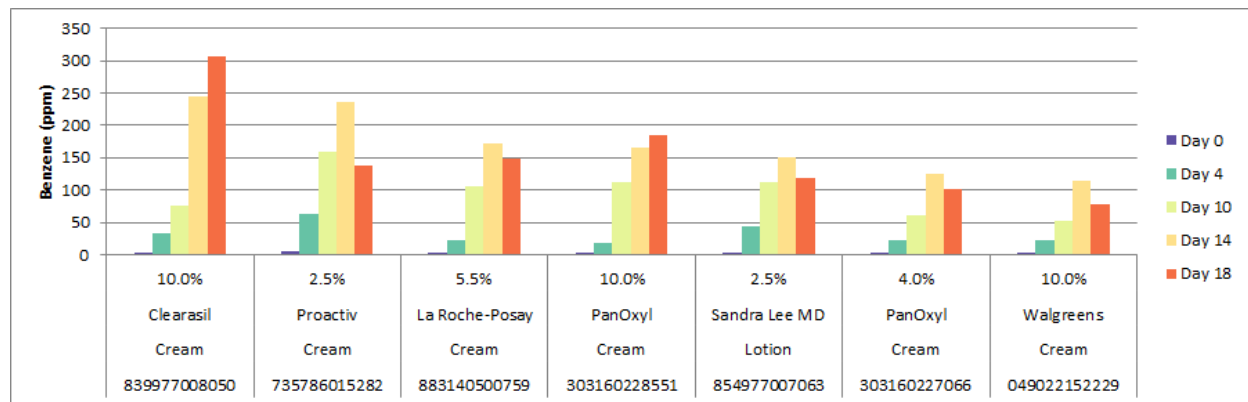
⁴² Grundstein A, Meentemeyer V, Dowd J. *Maximum vehicle cabin temperatures under different meteorological conditions*. Int J Biometeorol. 2009 May;53(3):255-61. doi: 10.1007/s00484-009-0211-x. Epub 2009 Feb 21. PMID: 19234721.

⁴³ Valisure, LLC, (March 6, 2024), *Valisure Discovers Benzoyl Acne Treatment Products are Unstable and Form Benzene*, <https://www.valisure.com/valisure-newsroom/valisure-detects-benzene-in-benzoyl-peroxide> (last visited March 6, 2024).

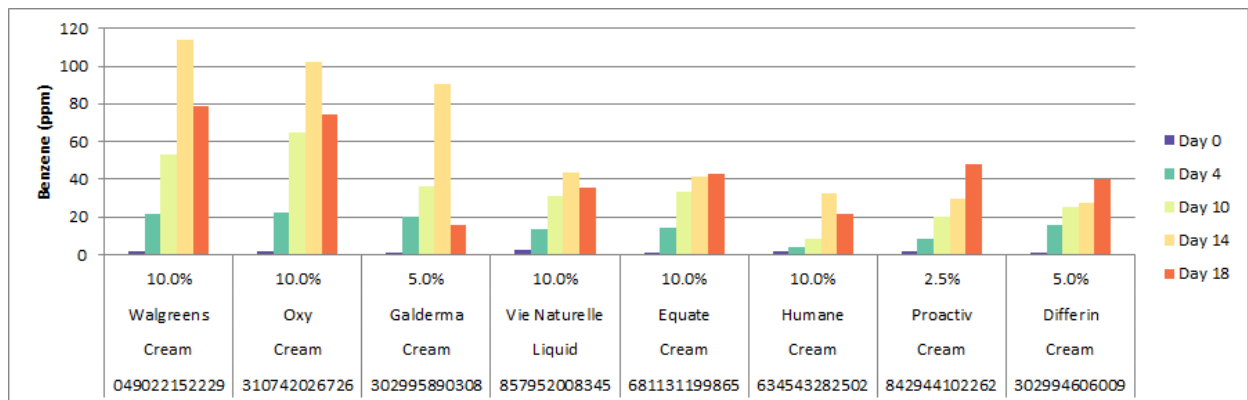
4A



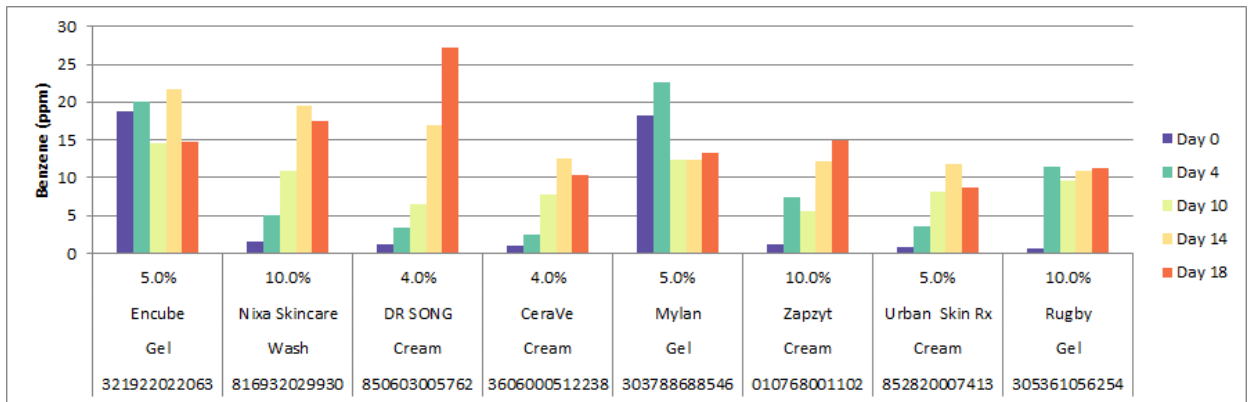
4B



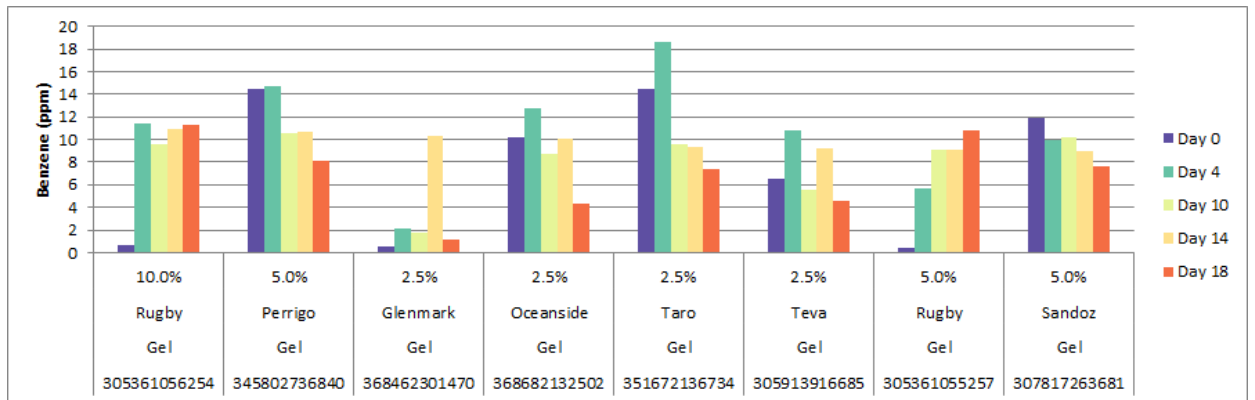
4C



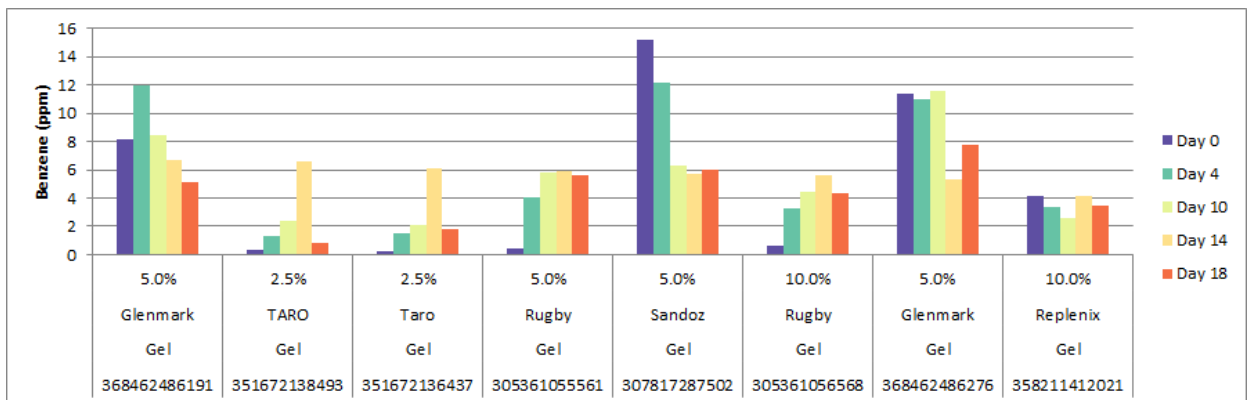
4D



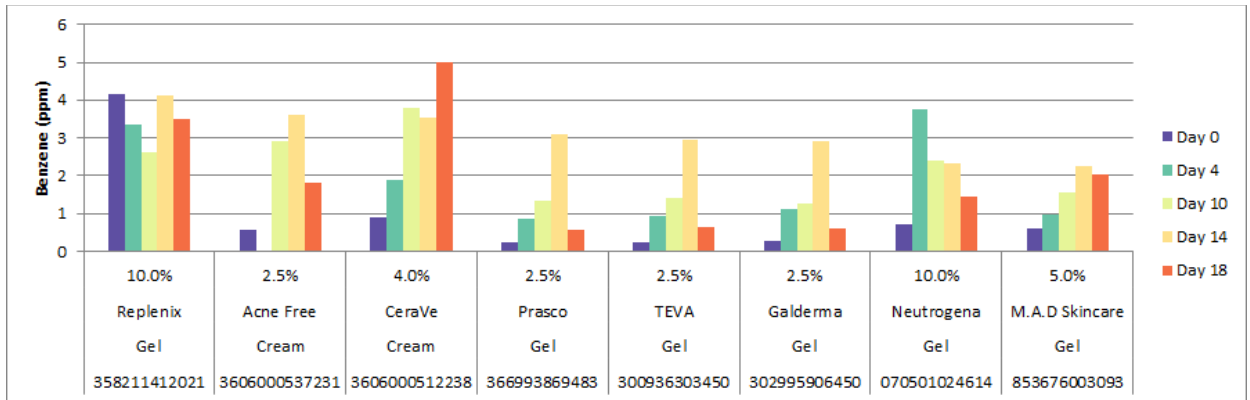
4E



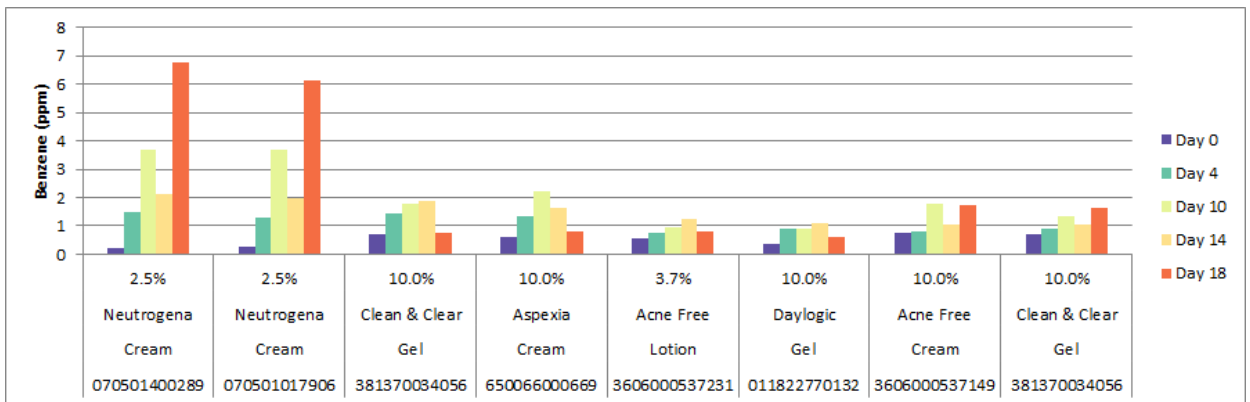
4F



4G



4H



49. Valisure found the BPO formulated products were not chemically stable and yielded benzene at levels well over 2 ppm, the maximum amount allowed in any U.S. regulated drug. Some of the benzene levels were 800 times higher than 2 ppm reaching as high as 1700 ppm.⁴⁴ The concentration of BPO in the Products did not influence the benzene levels. Unexpectedly, Valisure found that benzene vapors leaked from some of the tested Products' packaging contaminating the surrounding air even when the packaging was closed raising concern for additional inhalation exposures.⁴⁵

50. Valisure concluded that all on-market BPO acne formulations are fundamentally unstable and form unacceptably high levels of benzene under normal use, handling, and storage temperatures, but no such evidence was observed for acne

⁴⁴ *Id.*

⁴⁵ *Id.*

1 treatment products not formulated with BPO.⁴⁶ The finding that additional benzene
 2 leaked into the surrounding air from the products' containers means the total consumer
 3 benzene exposure would be even more dangerous than the levels reported.

4 51. Valisure filed a Citizen's Petition on Benzoyl Peroxide on March 5, 2024⁴⁷
 5 with the FDA requesting the FDA Commissioner to immediately demand a recall of all
 6 BPO Products formulated with BPO and further to require that drug manufacturers do
 7 independent chemical verification.

8 **G. JNJ EXPOSED CONSUMERS TO A RISK OF BENZENE**
 9 **EXPOSURE WITHOUT THEIR KNOWLEDGE**

10 52. Although benzene has been found in on-market BPO Products and released
 11 into the surrounding air from the certain Products' packaging, Defendant did not list
 12 benzene among its Products' ingredients, on the Products' label or container, or
 13 anywhere in advertising or on its websites. Defendant did not warn that the Products
 14 contain benzene, are at risk of benzene contamination, or that the Products could cause
 15 consumers to be exposed to benzene even when the container and packaging is sealed.

16 53. Benzene is a carcinogen that has been among the most studied toxins over
 17 the last 100 years due to its wide use during the industrial revolution, extreme danger,
 18 and known ability to cause cancer and death in humans and animals. The medical
 19 literature linking benzene to blood cancers is vast dating to the 1930s.⁴⁸ Benzene is the
 20 foundation component for many chemicals used to make plastics, resins, synthetic
 21 fibers, paints, dyes, detergents, drugs, and pesticides. In the past, benzene was widely
 22 used as a solvent in industrial paints, paint removers, adhesives, degreasing agents,
 23

24 ⁴⁶ *Id.*

25 ⁴⁷ As of the date of filing this Class Action, Valisure's FDA Petition is still pending.

26 ⁴⁸ See Hamilton A., *Benzene (benzol) poisoning*, ARCH PATHOL, (1931):434-54, 601-37; Hunter FT, *Chronic*
 27 *exposure to benzene (benzol). Part 2: The clinical effects*. J. IND. HYG TOXICOL, (1939):21 (8) 331-54;
 28 Mallory TB, et al., *Chronic exposure to benzene (benzol).Part 3:The pathological results*. J. IND. HYG
 TOXICOL,(1939):21 (8) 355-93; Erf LA, Rhoads CP., *The hematological effects of benzene (benzol)*
poisoning. J. IND. HYG TOXICOL, (1939):21 421-35; American Petroleum Institute, *API Toxicological*
Review: Benzene, NEW YORK, (1948); Infante PF, Rinsky RA, Wagoner JK, et al., *Leukemia in benzene*
workers,LANCET, (1977);2 (8028): 76-78.

1 denatured alcohol, and rubber cements. Benzene use has declined due to the
 2 proliferation of worker studies and an ever-growing body of evidence confirming
 3 benzene's contribution to blood cancers.

4 54. Benzene has no known safe level of exposure.⁴⁹ Benzene causes central
 5 nervous system depression and destroys bone marrow, leading to injury in the
 6 hematopoietic system.⁵⁰ The International Agency for Research on Cancer ("IARC")
 7 classifies benzene as a "Group 1 Carcinogen" that causes cancer in humans, including
 8 acute myelogenous leukemia ("AML").⁵¹ AML is the signature disease for benzene
 9 exposure with rates of AML particularly high in studies of workers exposed to
 10 benzene.⁵²

11 55. Benzene exposure is cumulative and additive. There is no safe level of
 12 exposure to benzene, and all exposures constitute some risk in a linear, if not
 13 supralinear, and additive fashion."⁵³

14 56. The Agency for Toxic Substances and Disease Registry's ("ATSDR")
 15 "Tox Facts" for benzene warns that people can be exposed to benzene vapors from
 16 benzene-containing products and that benzene harms the blood marrow, causing
 17 leukemia and anemia, and affects the immune system leaving victims vulnerable to
 18 infection.⁵⁴

19 57. According to the FDA, benzene in small amounts over long periods of time
 20 can decrease the formation of blood cells and long-term exposure through inhalation,
 21 oral intake, and skin absorption may result in cancers such as leukemia and other blood
 22

23 ⁴⁹ Harrison R, Saborit, J., *WHO Guidelines for Indoor Air Quality – Selected Pollutants*, (2010); see also
 24 Smith, Martyn T. (2010). Advances in Understanding Benzene Health Effects and Susceptibility. *Annual
 Review of Public Health*, (2010) Vol. 31:133-148.

25 ⁵⁰ FDA Toxicological Data for Class 1 Solvents, Appendix 4, *Benzene*,
<https://www.fda.gov/media/71738/download>.

26 ⁵¹ International Agency for Research on Cancer. *Benzene, IARC Monographs on the Evaluation of
 Carcinogenic Risks to Humans, Volume 120*, LYON, France: World Health Organization, (2018).

27 ⁵² American Cancer Association, *Benzene and Cancer Risk*, [https://www.cancer.org/cancer/risk-
 prevention/chemicals/benzene.html](https://www.cancer.org/cancer/risk-prevention/chemicals/benzene.html) (last visited October 20, 2023).

28 ⁵³ Smith, Martyn T., *Annual Review of Public Health*, ADVANCES IN UNDERSTANDING BENZENE
 HEALTH EFFECTS AND SUSCEPTIBILITY (2010) Vol. 31:133-148.

⁵⁴ Agency for Toxic Substances and Disease Registry, *Benzene – Tox Facts*, CAS # 71-43-2.

1 disorders.⁵⁵

2 58. Benzene is a major industrial chemical made from coal and oil that is
3 heavily regulated by the EPA as an important environmental pollutant that negatively
4 affects the soil, air, and groundwater. Waste and air emissions containing benzene are
5 considered hazardous waste. The coal, oil, paint, and chemical industries are heavily
6 regulated due to the emission of carcinogens including benzene from refining and other
7 industries processes involving benzene and benzene byproducts, which can end up in
8 the air, water, and food supply.

9 59. Benzene is heavily regulated to protect public health and should not be in
10 drug products, especially ones such as acne treatment that are used daily by children
11 and teenagers for many years. The FDA drug guidelines specify that benzene must not
12 be used to make drugs products because of the unacceptable toxicity and deleterious
13 environmental effects.⁵⁶ The FDA allows one limited exception – where the use of
14 benzene in a drug product is unavoidable to produce a drug product with a significant
15 therapeutic advance. In that instance, benzene must be restricted to two parts per
16 million (ppm).⁵⁷ Defendant’s BPO Products do not meet this rare exception.

17 60. Benzene is heavily regulated in the workplace. The U.S. Occupational
18 Safety and Health Administration (“OSHA”) set an eight-hour exposure standard of 1
19 ppm.⁵⁸ The National Institute for Occupational Safety and Health (“NIOSH”)
20 established a recommended exposure level (REL) of 0.1 ppm (15-minute ceiling limit).
21 Subsequent exposure studies known as the “China studies” confirmed cancer at levels
22 below 1 ppm.⁵⁹ The benzene levels created from Defendant’s BPO Products are many
23

24 ⁵⁵ Federal Drug Administration. (June 9, 2022). *Frequently Asked Questions*: <https://www.fda.gov/drugs/drug-safety-and-availability/frequently-asked-questions-benzene-contamination-drugs>.

25 ⁵⁶ Food and Drug Administration, *Q3C – Tables and Lists Guidance for Industry*,
<https://www.fda.gov/media/71737/download> (last visited September 26, 2023).

26 ⁵⁷ *Id.*

27 ⁵⁸ OSHA. Occupational exposure to benzene: Final rule. Fed. Reg. 1987;52-34460-578.

28 ⁵⁹ See Lan Q, Zhang L et al., *Hematotoxicity in Workers Exposed to Low Levels of Benzene*, SCIENCE, (December 3, 2004); Costa-Amaral I, V. B. L., *Environmental Assessment and Evaluation of Oxidative Stress and Genotoxicity Biomarkers Related to Chronic Occupational Exposure to Benzene*, INT J ENVIRON RES PUBLIC HEALTH, (2019) Jun; 16(12): 2240.

1 times higher than the levels reported in these worker studies and the acceptable limits
2 set by regulators.

3 61. Benzene can also pass from the mother's blood to a developing fetus
4 causing the baby to be exposed to benzene.⁶⁰ Animal studies have shown low birth
5 weights, delayed bone formation, and damage to the bone marrow of developing
6 offspring when pregnant animals breathed benzene.⁶¹

7 62. Plaintiffs and the Classes were exposed to benzene from the BPO Products
8 by inhalation and dermal absorption. Benzene can be absorbed into the body via
9 inhalation, skin absorption, ingestion, and/or eye contact.⁶² Plaintiffs and the Classes
10 applied the BPO Products to areas of the skin including the face, neck, chest, and back
11 one to three times per day and used the BPO Products as washes or scrubs in heated
12 showers. Plaintiffs and the Classes were also exposed to benzene leaked from
13 contaminated BPO Products.

14 **H. JNJ DIRECTLY MARKETING THE BPO PRODUCTS TO**
15 **CHILDREN AND TEENAGERS WITHOUT DISCLOSING THE**
16 **RISK OF BENZENE CONTAMINATION**

17 63. Defendant's BPO Products are widely used by children and teenagers as a
18 standalone treatment or in combination with other BPO Products. Defendant knew that
19 adolescents are the largest users with users as young as 7-10 years old. Defendant
20 recommended that consumers, including children, use the BPO Products one to three
21 times a day, over many months or longer for persistent acne. Defendant knew that some
22 consumers would use the BPO Products for many years starting in their teens. There is
23 no cure for acne. Defendant knew that consumers with chronic acne would use its BPO
24 Products several times a day throughout their lifetime.

25 64. Defendant aggressively marketed the BPO Products directly to children
26

27 ⁶⁰ *Id.*

28 ⁶¹ *Id.*

⁶² Centers for Disease Control and Prevention, *The National Institute for Occupational Safety and Health Pocket Guide to Chemical Hazards, Benzene Exposure Limits*, <https://www.cdc.gov/niosh/npg/npgd0049.html>.

1 and teenagers knowing, or they should have known, the BPO Products degrade to
2 benzene under normal use and storage conditions. Many of Defendant's online and
3 print advertisements featured children, teenagers, eye-catching props, music, and colors
4 meant to attract teens and pre-teens, and appeal to their preferences, activities, and
5 interests.

6 65. Defendant's marketing of BPO Products without mentioning benzene, the
7 risk of benzene exposure, or testing for benzene was misleading, fraudulent, deceptive,
8 and dangerous.

9 **V. PUNITIVE DAMAGES ALLEGATIONS**

10 66. Defendant's conduct was done with malice and reckless disregard for
11 human life. Defendant knew the BPO Products degraded to benzene when exposed to
12 normal consumer use, handling, and storage conditions. Defendant further knew that
13 benzene is a known human carcinogen that is not supposed to be in the BPO Products
14 due to the grave risk of harm to consumers. Defendant disregarded this information and
15 the known risks of benzene exposure and deliberately omitted benzene from the list of
16 ingredients, the BPO Products' labels, and its social media and websites where
17 information about the BPO Products is found. Defendant consciously and deliberately
18 crafted the BPO Products' marketing, labels, packaging, containers, and warnings
19 intending to mislead consumers and lead them to believe the BPO Products were safe
20 and carcinogen-free.

21 67. Defendant marketed themselves as expert drug formulators, researchers,
22 and sellers skilled in developing safe and reliable products. Defendant withheld
23 material health and safety information Defendant knew was essential to informed
24 consumer decision making. Defendant knew that, by its conduct, they were robbing
25 consumers and the public of their right to choose safe products.

26 68. Defendant was on notice of benzene findings in other consumer and drug
27 products leading to widely publicized recalls. Defendant was on notice of the FDA's
28 concerns of benzene contamination in drug and consumer products and received the

1 FDA's 2022 directive to test Products for benzene contamination. Defendant
2 disregarded these notices and continued to market and sell the BPO Products without
3 testing them for benzene.

4 69. Defendant knew its decisions and chosen course of conduct was risky and
5 would cause consumers to be exposed to benzene. Defendant's conduct was not by
6 accident, but was deliberate, calculated, and informed. Defendant knew they could sell
7 more BPO Products and earn more money by concealing material human health and
8 safety information. Defendant further knew that testing the BPO Products for benzene
9 would yield findings of benzene requiring recalls and/or a shutdown of production
10 causing significant losses of income. Defendant's goals were met not only because of
11 its false and deceptive advertising, labeling, and packaging, but through a
12 comprehensive scheme of aggressive marketing and image branding leading consumers
13 to believe they were acne treatment experts dedicated to drug research, development,
14 and safety and using only the safest ingredients and formulations that would remain
15 pure and stable until the designated end, *i.e.*, the expiration date. Defendant's conduct
16 and concealment of material health and safety information was done to further their
17 own monetary gain and with conscious disregard of the Consumers, and the public's
18 right to choose safe products. Defendant's conduct was intentional, calculated, blatantly
19 deceptive, unscrupulous, and offensive to consumer health and public policy. To
20 redress the harm caused by Defendant's conduct, Plaintiffs, on behalf themselves, the
21 Class, and Subclasses, seek punitive damages against the Defendant.

22 VI. PLAINTIFFS' SPECIFIC ALLEGATIONS

23 70. Plaintiff Alan Montenegro is a California resident who places a high
24 priority on health and safety, and on the adverse health consequences of exposure to
25 carcinogens such as benzene. In shopping for drug products for his skin and face,
26 Plaintiff Alan Montenegro was particularly concerned about the product being cost
27 effective, that the BPO Product received positive reviews from verified buyers, and the
28 before and after images for use of the Product. Plaintiff recalls seeing online

1 advertisements by Defendant before purchasing them in the store. Based on the
2 statements made by Defendant, its widely recognized name, and lack of information
3 that the BPO Products contained carcinogens such as benzene, Plaintiff believed the
4 Products were safe to put on his skin. Defendant's representations and omissions of
5 human health and safety information were material to Plaintiff.

6 71. Plaintiff Montenegro bought Neutrogena Rapid Clear Stubborn Acne Spot
7 Gel and used it from 2017 to 2021 in hopes of creating a daily skin routine and getting
8 rid of acne spots and blemishes. Plaintiff was unaware when he bought the BPO
9 Product that it was contaminated with benzene or that it could degrade to benzene. Had
10 Defendant been truthful and told Plaintiff he would be exposed to benzene and/or be at
11 increased risk of cancer, he would not have purchased Neutrogena Rapid Clear
12 Stubborn Acne Spot Gel.

13 72. Plaintiff Montenegro suffered an ascertainable economic loss because of
14 Defendant's statements and misrepresentations in that he bought the BPO Products he
15 would not have bought but for Defendant's statements and misrepresentations.

16 73. Plaintiff Melissa Medina is a Nevada resident who places a high priority on
17 health and safety, and on the adverse health consequences of exposure to carcinogens
18 such as benzene. In shopping for drug products for her skin and face, Plaintiff Melissa
19 Medina was particularly concerned about a product that was effective and safe to use to
20 help with the breakouts on her skin and face. Plaintiff read the front labeling of the
21 product which encouraged her to purchase the product by Defendant. Based on the
22 statements made by Defendant, its widely recognized name, and lack of information
23 that the BPO Products contained carcinogens such as benzene, Plaintiff believed the
24 BPO Products were safe to put on her skin. Defendant's representations and omissions
25 of human health and safety information were material to Plaintiff.

26 74. Plaintiff Medina bought Clean & Clear Continuous Control Acne Cleanser
27 and used it from September 2020 to May 2023 for her breakouts on her skin and face.
28 Plaintiff was unaware when she bought the BPO Product that it was contaminated with

1 benzene or that it could degrade to benzene. Had Defendant been truthful and told
2 Plaintiff she would be exposed to benzene and/or be at increased risk of cancer, she
3 would not have purchased Clean & Clear Continuous Control Acne Cleanser.

4 75. Plaintiff Medina suffered an ascertainable economic loss because of
5 Defendant's statements and misrepresentations in that she bought the BPO Products she
6 would not have bought but for Defendant's statements and misrepresentations.

7 **VII. CLASS ACTION ALLEGATIONS**

8 76. Plaintiffs bring this case on behalf of themselves, and all others similarly
9 situated as a Class Action under Rule 23 of the Federal Rules of Civil Procedure.
10 Plaintiffs seek to represent a National Class of consumers who bought the Products, and
11 State Subclasses of consumers from the states identified below. Excluded from this
12 Class are Defendant, its employees, co-conspirators, officers, directors, legal
13 representatives, heirs, successors, and affiliated companies; Class counsel and its
14 employees; and judicial officers and their immediate families as court staff assigned to
15 the case.

16 77. The Class does not seek damages for physical injuries, although Plaintiffs
17 were physically harmed by being exposed to benzene.

18 78. The Class will include a National Class to include all persons who bought
19 for use, and not resale, the BPO Products within the United States.

20 79. The State Subclasses will include all persons who bought for use, and not
21 resale, the BPO Products within California, Connecticut, Hawaii, Illinois, Maryland,
22 Massachusetts, Missouri, New York, Nevada, Ohio, Pennsylvania, Rhode Island, and
23 Washington.

24 80. This action has been brought and may be properly maintained as a Class
25 Action under Rule 23 of the Federal Rules of Civil Procedure because there is a well-
26 defined community of interest and the proposed Class meets the class action
27 requirements under Rule 23 of numerosity, commonality, typicality, and adequacy of
28 representation.

1 81. Defendant engaged in a common course of conduct giving rise to the legal
2 rights sought to be enforced by Plaintiffs, on behalf of themselves, and the other Class
3 members. Similar or identical statutory and common law violations, business practices,
4 and injuries are involved.

5 82. **Numerosity.** Plaintiffs believes there are millions of Class members
6 throughout the United States, and there are tens of thousands of Subclass members in
7 each of the listed states, making the Class and state Subclasses so numerous and
8 geographically dispersed that joinder of all members is inconvenient and impracticable.

9 83. **Commonality.** There are questions of law and fact common to all Class
10 members that predominate over questions which affect only individual Class members.
11 All Class members were deceived and misled by Defendant through the same
12 advertising, online representations, labeling, and packaging, which did not mention
13 benzene, and which misrepresented the characteristics, ingredients, and safety of the
14 BPO Products. All Class members bought Defendant's BPO Products and have
15 suffered an economic loss because of Defendant's deceptions and omissions of material
16 health and safety information. Thus, there is a well-defined community of interest in
17 the questions of law and facts common to all Class members. Other common questions
18 of law and fact in this dispute include, without limitation:

- 19 a. Whether Defendant's BPO Products degrade to benzene under common
20 distributor and consumer handling, use, and storage conditions.
- 21 b. Whether Defendant tested the BPO Products for benzene before selling
22 them to Plaintiffs, the Class, and the public.
- 23 c. When Defendant knew or should have known the BPO Products degraded
24 to benzene.
- 25 d. When Defendant knew or should have known the BPO Products contain
26 benzene.
- 27 e. Whether Defendant's advertising omitting benzene was deceptive,
28 fraudulent, or unfair.

- 1 f. Whether Defendant's advertising omitting benzene was likely to deceive
- 2 reasonable consumers.
- 3 g. Whether Defendant's conduct violated California's Unfair Competition
- 4 Law, Bus. & Prof. Code § 17200 *et seq.*
- 5 h. Whether Defendant's conduct violated California consumer protection laws.
- 6 i. Whether Defendant's conduct violated Connecticut consumer protection
- 7 laws.
- 8 j. Whether Defendant's conduct violated Hawaii consumer protection laws.
- 9 k. Whether Defendant's conduct violated Illinois consumer protection laws.
- 10 l. Whether Defendant's conduct violated Massachusetts consumer protection
- 11 laws including Mass. Gen. Laws Ann. Ch. 93A, § 1 *et seq.*
- 12 m. Whether Defendant's conduct violated Maryland consumer protection laws.
- 13 n. Whether Defendant's conduct violated Missouri consumer protection laws
- 14 including Mo. Rev. Stat. § 407, *et seq.*
- 15 o. Whether Defendant's conduct violated Nevada consumer protection laws
- 16 including Deceptive Trade Practice Act, NEV. REV. STATUTES, Title 52,
- 17 Chapter 598 *et seq.*
- 18 p. Whether Defendant's conduct violated New York consumer protection laws
- 19 including New York Deceptive Trade Practices Law, NY Gen. Bus. §349(a)
- 20 and NY Gen. Bus. §§ 350 *et seq.*
- 21 q. Whether Defendant's conduct violated Pennsylvania consumer protection
- 22 laws.
- 23 r. Whether Defendant's conduct violated Ohio consumer protection laws.
- 24 s. Whether Defendant's conduct violated Rhode Island consumer protection
- 25 laws.
- 26 t. Whether Defendant's conduct violated Washington's consumer protection
- 27 laws.
- 28 u. Whether Defendant breached the express and implied warranties they made

1 about the BPO Products.

2 v. Whether Defendant was unjustly enriched by the Plaintiffs and the Class
3 members purchase of the BPO Products.

4 w. Whether the Plaintiffs and the Class members have been injured and if so,
5 what is the proper measure of damages.

6 x. Whether the Plaintiffs and the Class members have the right to economic
7 damages including compensatory, exemplary, and statutory remedies for
8 Defendant's misconduct.

9 y. Whether the Plaintiffs and the Class members have the right to injunctive,
10 declaratory, or other equitable relief and attorneys' fees.

11 **84. Typicality.** Plaintiffs' claims are typical of the claims of the Class because
12 the claims arise from the same course of misconduct by Defendant, *i.e.*, Defendant's
13 false and misleading advertising and its failure to disclose benzene in the Products.
14 The Plaintiffs, and all Class members were all exposed to the same uniform and
15 consistent advertising, labeling, and packaging statements Defendant made about the
16 Products. Because of the Defendant's misconduct, Plaintiffs, like all Class members,
17 were damaged and have incurred economic losses because they bought the Products
18 believing they were safe. The claims of the Plaintiffs are typical of all Class members.

19 **85. Adequacy.** The Plaintiffs will fairly and adequately represent and protect
20 the interests of all Class members. Plaintiffs have no interests antagonistic to the Class
21 members. Plaintiffs hired attorneys experienced in the prosecution of consumer Class
22 Actions and Plaintiffs intend to prosecute this action vigorously. Plaintiffs anticipate no
23 difficulty in the management of this litigation as a Class Action.

24 **86.** Finally, this Class Action is proper under Rule 23(b) because, under these
25 facts, a Class Action is superior to other methods and is the most efficient method for
26 the fair and efficient adjudication of the dispute. The Class members have all suffered
27 economic damages because of Defendant's deceptive trade practices, false advertising,
28 and omissions of material health and safety information. Because of the nature of the

individual Class members' claims and the cost of the Products, few, if any individuals, would seek legal redress against Defendant because the costs of litigation would far exceed any potential economic recovery. Absent a Class Action, individuals will continue to suffer economic losses for which they would have no remedy, and Defendant will unjustly continue its misconduct with no accountability while retaining the profits of its ill-gotten gains. Even if separate cases could be brought by individuals, the resulting multiplicity of lawsuits would cause undue hardship, burden, and expense for the Court and the litigants, as well as create a risk of inconsistent rulings across the country, which might be dispositive of the interests of individuals who are not parties. A Class Action furthers the important public interest of containing legal expenses, efficiently resolving many claims with common facts in a single forum simultaneously, and without unnecessary duplication of effort and drain on critical judicial resources. The Class Action method presents far fewer management difficulties than individual cases filed nationwide and provides the benefit of comprehensive supervision by a single court.

VIII. CAUSES OF ACTION

A. VIOLATION OF CALIFORNIA'S UNFAIR COMPETITION LAW **BUS. & PROF. CODE § 17200 *et seq.*, Individually and on Behalf of the** **California Subclass**

87. Plaintiffs reallege and incorporates all other paragraphs in this Class Action Complaint and further allege:

88. Plaintiffs bring this cause of action on behalf of themselves, and all members of the California Subclass, all of whom are similarly situated consumers.

89. California's Unfair Competition Law, CAL. BUS. & PROF. CODE § 17200, *et seq.*, prohibits "unlawful, unfair, or fraudulent business act or practices" and "unfair, deceptive, untrue or misleading advertising." Defendant misrepresented its Products in advertising, labels, and containers and misled Plaintiffs, the Subclass, and the public about the ingredients, characteristics, purity, quality, approval, and safety of the

1 Products. Defendant led Plaintiffs and the California Subclass to believe the Products
2 were safe.

3 90. Defendant's advertising, online representations, labeling, and packaging of
4 the Products were misleading, fraudulent, and deceptive. Defendant knew through the
5 Products' development, formulation, research, and pre-sale safety and stability testing,
6 the Products were not chemically and physically stable when exposed to common
7 temperature conditions. Defendant knew or should have known the Products
8 formulated benzene under normal and expected consumer use, handling, and storage
9 conditions, and that consumers would be exposed to benzene. Defendant were
10 specifically reminded by the FDA of its obligation to ensure the safety and quality of its
11 Products, including testing them for benzene before selling them to the public, but
12 shirked its duties and continued to market and sell the Products without substantiating
13 its safety, or warning Plaintiffs and the California Subclass about benzene.

14 91. Defendant omitted material health and safety information, *e.g.*, benzene,
15 from the Products' advertising, label, container, and warnings. Defendant did not tell
16 Plaintiffs and the California Subclass they would be exposed to benzene, a human
17 carcinogen, during normal and expected handling, use and storage of the Products, even
18 with the Products' container closed.

19 92. Defendant's acts and omissions were likely to deceive reasonable
20 consumers and the public. Reasonable consumers expect to be told about all ingredients
21 in Products. Reasonable consumers further expect that carcinogens in the Products be
22 disclosed. Reasonable consumers further expect that on market drugs to be free of
23 carcinogens, unless told otherwise. Benzene in a widely marketed drug product used by
24 children, teens, and the public is material health information reasonable consumers
25 expect to be told.

26 93. Had Defendant been truthful in its advertising, labeling, packaging, and
27 online statements about benzene in the Products, or the risk of contamination, and the
28 risk of cancer, Plaintiffs and the Class members would not have bought the Products.

94. Defendant's acts, omissions, and concealment of material health and safety information are ongoing and continuing to cause harm. Defendant continued to market, advertise, and sell the Products to the public without telling the public about benzene in the Products, or the risk of contamination, and the risk of cancer. Defendant continued to market themselves as responsible drug manufacturers and sellers who sell safe products when they have not tested the Products for benzene or quantified the levels of benzene formed in the Products during normal and expected storage conditions.

95. Defendant engaged in these deceptive practices for significant financial gain, which is unfair, unreasonably dangerous to Plaintiffs and the California Subclass and not outweighed by any benefit. Omitting and concealing material human health and safety information such as benzene in the Product and the consumers' risk of cancer from the Products is unethical, unscrupulous, and offensive.

96. Plaintiffs suffered ascertainable economic losses because of Defendant's misconduct because they bought the Products, they otherwise would not have bought but for Defendant's misrepresentations and affirmations of safety.

97. Because of Defendant's misconduct, Plaintiffs, on behalf of themselves, and the California Subclass, seek recovery of their economic damages, attorneys' fees, restitution, and all other relief allowable under CAL. BUS. & PROF. CODE § 17200, *et seq.*, including an injunction to enjoin Defendant from continuing its fraudulent and deceptive business practices. The damages sought are ascertainable, uniform and can be measured and returned to the Plaintiffs and the California Subclass members.

B. VIOLATION OF CALIFORNIA'S CONSUMER LEGAL REMEDIES ACT, Cal. Civ. Code § 1750, et seq., Individually and on Behalf of the California Subclass

98. Plaintiffs reallege and incorporates all other paragraphs in this Complaint and further allege:

99. Plaintiffs bring this cause of action on behalf of themselves, and all Class California Subclass members, all of whom are similarly situated consumers within the

1 meaning of CAL. CIV. CODE § 1781.

2 100. Defendant's acts and omissions violated California's Consumer Legal
3 Remedies Act, CAL. CIV. CODE § 1750, *et seq.*, enacted to protect consumers from
4 being victimized and deceived by advertisers, distributors, and sellers like the
5 Defendant. Other Defendant regularly transact business in California, including in this
6 District, and have engaged in misconduct that has and had a direct, substantial,
7 foreseeable, and intended effect of injuring people in California, and in this District.

8 101. California's Consumer Legal Remedies Act, CAL. CIV. CODE § 1750, *et*
9 *seq. prohibits* unfair methods of competition and unfair or deceptive acts or practices in
10 connection with the sale of consumer goods. Defendant violated several prohibitions of
11 CIV. CODE § 1750(a).

12 102. Defendant violated CAL. CIV. CODE § 1750(a)(2) by representing the
13 source, sponsorship, and approval, of the Products, *e.g.*, the Products were backed by
14 sound scientific principles, that Defendant met its obligations to conduct adequate and
15 meaningful quality and safety testing before selling the Products to the public, and
16 represented the Products only contained the ingredients listed, and were free of
17 carcinogens.

18 103. Defendant violated CAL. CIV. CODE § 1750(a)(3) by representing the
19 affiliation, connection, or association with, or certification by, another *e.g.*, the Products
20 were approved by dermatologists and manufactured in conformity with current good
21 manufacturing practices.

22 104. Defendant violated CAL. CIV. CODE § 1750 (a)(4) by using deceptive
23 representations, *e.g.*, the Products were safe, validated, and supported by the latest
24 research, and free of carcinogens such as benzene.

25 105. Defendant violated CAL. CIV. CODE § 1750(a)(5) by representing the
26 Products have characteristics, ingredients, uses, or benefits, which they do not, *e.g.*,
27 misleading Plaintiffs and the Class members the Products only contained the listed
28 ingredients, did not contain benzene, and did not increase the risk of the consumers'

1 risk of cancer.

2 106. Defendant violated CAL. CIV. CODE § 1750(a)(6) by representing the
3 Products were not deteriorated unreasonably or altered *e.g.*, the Products were pure and
4 had not degraded or formed benzene.

5 107. Defendant violated CAL. CIV. CODE § 1750(a)(7) by representing the
6 Products were pure and of a particular standard or quality, when they are not.

7 108. Defendant violated CAL. CIV. CODE § 1750(a)(9) by advertising the
8 Products with the intent not to sell them as advertised, *e.g.*, the Products were of pure
9 quality, safe, made in conformity with current good manufacturing practices, and not
10 adulterated.

11 109. Had Defendant been truthful in its advertising, labeling, packaging,
12 warnings, and online statements about benzene in the Products and the risk of cancer,
13 Plaintiffs and the California Subclass would not have bought the Products. Benzene, a
14 human carcinogen, in a widely marketed and available consumer drug product, is
15 material health and safety information Defendant knew Plaintiffs and the California
16 Subclass would want to know. The Defendant's omission of this material information
17 was common to all Plaintiffs and the California Subclass members and made to all
18 Plaintiffs and the California Subclass members uniformly through common advertising,
19 online representations, labeling, and packaging.

20 110. Defendant's acts, omissions, and concealment of material health and safety
21 information are ongoing and continuing to cause harm. Defendant continued to market,
22 advertise, and sell the Products to the Plaintiffs and the California Subclass without
23 telling the public about benzene in the Products and the risk of cancer. Defendant
24 continued to market themselves as responsible drug manufacturers and sellers who sell
25 safe products when they have not quantified the levels of benzene in and created in the
26 Products during normal and expected storage conditions.

27 111. Defendant engaged in these deceptive practices for significant financial
28 gain, which is unfair, unreasonably dangerous to Plaintiffs and the California Subclass

1 and not outweighed by any benefit. Omitting and concealing material human health and
 2 safety information such as the consumers' risk of cancer from exposure to the Products
 3 is unethical, unscrupulous, and offensive.

4 112. Plaintiffs and the California Subclass members suffered ascertainable
 5 economic losses because of Defendant's misconduct because they bought the Products,
 6 they otherwise would not have but for Defendant's misrepresentations.

7 113. Because of Defendant's misconduct, Plaintiffs, on behalf of themselves and
 8 the California Subclass members, seek recovery of their economic damages, attorneys'
 9 fees, punitive damages, restitution, and all other relief allowable under CAL. CIV. CODE
 10 § 1750, *et seq.*, including an injunction to enjoin Defendant from continuing its
 11 fraudulent business practices. The damages sought are ascertainable, uniform to the
 12 Subclass and can be measured and returned to the Plaintiffs and the California Subclass
 13 members.

14 **C. FALSE ADVERTISING UNDER VARIOUS STATE STATUTES,**
 15 **Individually and on Behalf of the California, Hawaii, and New York**
 16 **Subclasses**

17 114. Plaintiffs reallege and incorporates all other paragraphs in this Complaint
 18 and further allege:

19 115. Plaintiffs bring this cause of action on behalf of themselves, and all
 20 members of the California, Hawaii, and New York Subclasses, all of whom are
 21 similarly situated consumers.

22 116. Defendant develops, manufactures, tests, markets, and sells the BPO
 23 Products throughout the United States. Defendant knew through the Products'
 24 development, formulation, and testing, the Products were not chemically stable when
 25 exposed to certain expected and normal environmental and storage conditions and
 26 could form benzene, as a toxic byproduct. Despite this knowledge, Defendant did not
 27 mention benzene in the Products' advertising, ingredient list, label, container, or
 28 warnings. Defendant did not tell Plaintiffs, and the Subclass members they would be

1 exposed to benzene, a human carcinogen, during normal and expected handling, use
2 and storage of the Products, even with the Products' containers closed.

3 117. Benzene, a human carcinogen, in a widely marketed and available
4 consumer drug product, is material health and safety information Defendant knew
5 Plaintiffs and the Subclass members would want to know. Defendant not only omitted
6 this material human health and safety information from advertising, online
7 representations, blogs, labeling, packaging, and warnings, but Defendant aggressively
8 marketed themselves as drug experts, innovators, researchers, market leaders, and
9 committed to consumer safety. Defendant's affirmations of safety and responsibility
10 misled Plaintiffs, and the Subclass members, leading them to believe the Products were
11 tested, verified, and safe. Defendant further marketed the Products touting the approval
12 of dermatologists, who were not aware of the presence of benzene in the Products and
13 of Defendant's refusal to conduct adequate and meaningful testing before marketing
14 and selling the Products to the public and following the FDA's 2022 alert to
15 specifically look for benzene.

16 118. Defendant's acts and omissions constitute false advertising. Defendant
17 advertised the Products with the intent not to sell them as advertised. Reasonable
18 consumers, including Plaintiffs and the Subclass members, exposed to Defendant
19 advertising would believe the Products were safe, verified, and free of benzene.

20 119. Defendant's false and misleading advertising violated California's False
21 Advertising Law, Bus. & Prof. Code § 17500 *et seq.*, which prohibits Defendant from
22 disseminating statements "which are untrue or misleading, and which are known, or
23 which by the exercise of reasonable care should be known, to be untrue or misleading."
24 Defendant knew or should have known the Products formed benzene under normal,
25 handling, use, and storage conditions but did not disclose this to Plaintiffs and the
26 Subclass members. Defendant knew Plaintiffs, the Class members, and consumers
27 would be exposed to benzene in the Products, even with the Products' original
28 packaging closed.

120. Defendant's false and misleading advertising violated Hawaii's False Advertising Law, HI REV. STAT. § 708-871. Defendant knowingly or recklessly made false and misleading statements in the Products' advertising to the public.⁶³ Defendant further advertised the Products with the intent not to sell them as advertised and misrepresented the ingredients, quality, purity, safety, and character of the Products.

121. Defendant's false and misleading advertising violated New York's General Business Law § 350 *et seq.* ("GBL § 350"), which prohibits "[f]alse advertising in the misconduct of any business, trade or commerce or in the furnishing of any service" in New York. Under GBL § 350, "false advertising" includes "advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect." Defendant violated GBL § 350 by advertising and selling the Products without disclosing material health and safety information, *e.g.*, benzene and the consumers risk of cancer from benzene. Defendant's false and misleading advertising was directed at consumers, the New York Subclass members, and the public, and caused consumer injury and harm to the public interest.

122. Had Defendant been truthful in its advertising, online representations, labeling, and packaging about benzene, Plaintiffs and the Subclass members would not have bought the Products.

123. Plaintiffs, on behalf of themselves, and the California, Hawaii and New York Subclasses suffered ascertainable economic losses because of Defendant's misconduct because they bought the Products, they otherwise would not have but for Defendant's material misrepresentations.

124. Because of Defendant's misconduct, Plaintiffs, on behalf of themselves and the California, Hawaii, and New York Subclasses, seek recovery of their economic

⁶³ HI REV STAT § 708-871, False Advertising: (1) A person commits the offense of false advertising if, in connection with the promotion of the sale of property or services, the person knowingly or recklessly makes or causes to be made a false or misleading statement in any advertisement addressed to the public or to a substantial number of persons. (2) "Misleading statement" includes an offer to sell property or services if the offeror does not intend to sell or provide the advertised property or services: (a) At the price equal to or lower than the price offered; or (b) In a quantity sufficient to meet the reasonably- expected public demand unless quantity is specifically stated in the advertisement; or (c) At all.

1 damages, attorneys' fees, punitive damages, restitution, and all other relief allowable by
 2 law, including an injunction to enjoin Defendant from continuing its fraudulent
 3 business practices. The damages sought are ascertainable, uniform to the Subclasses
 4 and can be measured and returned to the Plaintiffs and Subclass members.

5 **D. DECEPTIVE TRADE PRACTICES UNDER VARIOUS STATE**
 6 **STATUTES, Individually and on Behalf of California, Connecticut,**
 7 **Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York,**
 8 **Nevada, Pennsylvania, Ohio, Rhode Island, and Washington**
Subclasses

9 125. Plaintiffs reallege and incorporates all other paragraphs in this Complaint
 10 and further allege:

11 126. Plaintiffs bring this cause of action on behalf of themselves, and all
 12 members of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts,
 13 Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington
 14 Subclasses, all of whom are similarly situated consumers.

15 127. Defendant's acts and omissions constitute deceptive business practices in
 16 violation of state deceptive trade practices laws.

17 128. Defendant represented the BPO Products had characteristics, uses, and
 18 benefits, they did not, *e.g.*, Defendant represented the BPO Products were pure, of good
 19 quality, safe, and only contained the ingredients disclosed.

20 129. Defendant represented the BPO Products were not deteriorated or altered,
 21 when they knew, or should have known, the BPO Products degraded to benzene under
 22 normal and expected use, handling, and storage conditions.

23 130. Defendant represented the BPO Products contained only the ingredients
 24 listed on Defendant's websites, advertising, labels, and containers. Defendant did not
 25 disclose to Plaintiffs, the Subclasses, and the public that the BPO Products were at risk
 26 of benzene contamination.

27 131. Defendant advertised the BPO Products with the intent not to sell them as
 28 advertised.

1 132. Defendant's acts and omissions violated California's Consumer Legal
2 Remedies Act, CAL. CIV. CODE § 1750, *et seq.*, enacted to protect consumers from
3 being victimized and deceived by advertisers, distributors, and sellers like the
4 Defendant.

5 133. Defendant's acts and omissions violated Connecticut Unfair Trade
6 Practices Act, CONN. GEN STAT. ANN., § 42- 110, *et seq.*, which broadly prohibits
7 Defendant from engaging in unfair methods of competition and unfair or deceptive acts
8 or practices in the conduct of any trade or commerce such as those committed by
9 Defendant and alleged in this Class Action.

10 134. Defendant's acts and omissions violated Hawaii's Uniform Deceptive
11 Trade Practice Act, HAW. REV. STAT. §481-A3 because Defendant: (1) caused the
12 likelihood of confusion or of misunderstanding as to the source, sponsorship, approval,
13 or certification of the Products; (2) represented the Products had characteristics,
14 ingredients, or benefits, they did not; (3) represented the Products were not deteriorated
15 or altered, when they were; (4) represented the Products were of a particular standard
16 or quality when they were not; and (5) advertised the Products with the intent not to sell
17 them as advertised.

18 135. Defendant's acts and omissions violated Illinois' Consumer Fraud and
19 Deceptive Business Practices Act, 815 ILCS 505/1 *et seq.* Defendant's used deception,
20 fraud, false pretense, false promises, and omitted material health and safety information
21 about the Products' degradation to benzene, and/or contamination with benzene, which
22 Defendant intended the Illinois Subclass members to rely upon.

23 136. Defendant's acts and omissions violated Maryland's Unfair or Deceptive
24 Trade Practices Act, MD. COM. CODE, Title 13, Subtitle 3, §13-301 because Defendant:
25 (1) represented the Products had characteristics, ingredients, uses, and benefits, they did
26 not; (2) represented the Products were not deteriorated or altered, when they were; (3)
27 represented the Products were of a particular standard or quality, when they were not.
28 Defendant's representations about the Products' ingredients, and omission of benzene

1 were misleading, deceptive, incomplete, and not truthful in violation of Maryland's
2 Unfair or Deceptive Trade Practices Act.

3 137. Defendant's acts and omissions violated Massachusetts consumer
4 protection law, MASS. GEN. LAWS ANN. Ch. 93A, § 1 *et seq.*, which broadly prohibits
5 unfair and deceptive trade practices such as those committed by Defendant and alleged
6 in this Class Action.

7 138. Defendant's acts and omissions violated the Missouri Merchandising
8 Practices Act, MO. REV. STAT. § 407, *et seq.*, which prohibits the use of deception,
9 fraud, misrepresentations, or unfair practices by a business, *e.g.*, marketing Products as
10 safe, approved, tested, and only containing the listed ingredients. Missouri's law further
11 prohibits the suppression or omission of material facts such as the Products'
12 degradation to benzene.

13 139. Defendant's acts and omissions violated N.Y. GEN. BUS. LAW § 349, which
14 prohibits Defendant from engaging in deceptive, unfair, and misleading acts and
15 practices such as those committed by Defendant and alleged in this Class Action.
16 Defendant's misrepresentations and omissions caused consumer injury and harm to the
17 public interests of protecting public health and the public's right to know about any
18 harmful constituents in the Products.

19 140. Defendant's acts and omissions violate Nevada Deceptive Trade Practice
20 Act, NEV. REV. STATUTES, Title 52, Chapter 598 *et seq.* which prohibits Defendant
21 from making false statements about its Products and advertising the Products without
22 the intent to sell them as advertised.

23 141. Defendant's acts and omissions acts and omissions violated Ohio's
24 Consumer Sales Practices Act, OHIO REV. CODE ANN. § 1345.01, *et seq.* which
25 prohibits sales practices that are deceptive, unfair, or unconscionable, and Ohio's
26 Deceptive Trade Practices Act, OHIO REV. CODE ANN. § 4165 *et seq.*

27 142. Defendant's acts and omissions violated Pennsylvania's Unfair Trade
28 Practices and Consumer Protection Law, 73 P.S. §§201-1 *et seq.* because Defendant:

(1) caused the likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the Products; (2) used deceptive representations about the Products; (3) represented the Products had characteristics, ingredients, or benefits, they did not; (3) represented the Products were not deteriorated or altered, when they were; (4) represented the Products were particular standard or quality when they are not; and (5) advertised the Products with the intent not to sell them as advertised.

143. Defendant's acts and omissions violated Rhode Island's Deceptive Trade Practices Act, R.I. GEN. LAWS § 6- 13.1- 5.2(B), *et seq.* because Defendant: (1) caused likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of the Products; (2) used deceptive representations in connection with the Products; (3) represented the Products had sponsorship, approval, characteristics, ingredients, uses, benefits, they did not; (4) represented the Products were not deteriorated or altered, when they were; (5) represented the Products were of a particular standard, quality, or grade, when they were not; and (6) advertised the Products with the intent not to sell them as advertised.

144. Defendant's acts and omissions violated Washington's Consumer Protection Act, WASH. REV. CODE § 19.86.010, *et seq.*, which broadly prohibits Defendant from engaging in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce.⁶⁴ Defendant's concealment of material health and safety information about the Products, which they knew or should have known, was injurious to the public interests of protecting public health and the public's right to know about any harmful constituents in the Products. Defendant's conduct caused harm to the Plaintiffs, the Washington Subclass members, and members of the public who bought the Products without knowing they degraded to benzene. Defendant's conduct has the capacity to cause harm to other people who buy the

⁶⁴ Under § 19.86.090, Washington consumers harmed by such practices may recover actual damages, the costs of the suit, including reasonable attorney's fees, and the court may, in its discretion, increase the award of damages to an amount up to three times the actual damages sustained.

1 Products.

2 145. Had Defendant been truthful in its advertising, labeling, and packaging of
3 the Products and not omitted material health and safety information about benzene in
4 and formed from the Products, Plaintiffs and the Subclass members would not have
5 bought the Products.

6 146. Defendant's acts and omissions and violations of the state consumer
7 protection statutes are ongoing and continuing to cause harm.

8 147. Plaintiffs, on behalf of themselves, and members of the California, Hawaii,
9 Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio,
10 Rhode Island, and Washington Subclasses suffered an ascertainable economic loss
11 because of Defendant's misconduct because they bought the Products, they would not
12 have bought but for Defendant's misrepresentations.

13 148. Because of Defendant's misconduct, Plaintiffs, on behalf of themselves,
14 and the Subclasses, seek recovery of their economic damages, attorneys' fees, punitive
15 damages, and all other relief allowable under the law. The damages sought are
16 ascertainable, uniform to the Subclasses and can be measured and returned.

17 **E. BREACH OF EXPRESS WARRANTY, Individually and on Behalf of**
18 **the Nationwide Class and on Behalf of the California, Connecticut,**
19 **Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York,**
20 **Nevada, Pennsylvania, Ohio, Rhode Island, and Washington**
Subclasses

21 149. Plaintiffs reallege and incorporates all other paragraphs in this Complaint
22 and further allege:

23 150. Plaintiffs bring this cause of action on behalf of themselves, and all
24 members of the National Class and the California, Connecticut, Hawaii, Illinois,
25 Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode
26 Island, and Washington Subclasses, all of whom are similarly situated consumers.

27 151. The Uniform Commercial Code § 2-313 provides that an affirmation of
28 fact or promise made by the seller to the buyer which relates to the goods and becomes

1 part of the basis of the bargain creates an express warranty that the goods shall conform
 2 to the promise. Defendant advertised and sold the Products as safe, pure, of good
 3 quality, and only containing the listed ingredients. Defendant's advertising, labels,
 4 containers, packaging, advertising, and online statements did not mention benzene,
 5 leading consumers to believe the Products were safe for their ordinary use. Defendant's
 6 affirmations were uniformly made to Plaintiffs and the Class members by Defendant in
 7 the Products' advertising, labeling, packaging, and online statements and were part of
 8 the basis of the bargain between Defendant, the Plaintiffs, the Class, and Subclass
 9 members.

10 152. Defendant's affirmations and promises are unlawful. When Defendant
 11 marketed, distributed, and sold the Products, Defendant knew, or should have known,
 12 the Products degraded to benzene under normal and expected use, handling, and storage
 13 conditions. Defendant knew, or should have known, the Products formed benzene and
 14 therefore did not conform to Defendant's express representations and warranties to
 15 consumers. Plaintiffs, the Class, and Subclass members purchased the Products in
 16 reasonable reliance on Defendant's statements.

17 153. Because of Defendant's misconduct, Plaintiffs, on behalf of themselves, the
 18 Class and Subclass members, seek recovery of their economic damages, attorneys' fees,
 19 punitive damages, restitution, and all other relief allowable by law, including an
 20 injunction to enjoin Defendant from continuing its fraudulent business practices. The
 21 damages sought are ascertainable, uniform to the Class and Subclasses and can be
 22 measured and returned.

23 **F. BREACH OF IMPLIED WARRANTY, Individually and on Behalf of**
 24 **the Nationwide Class and on Behalf of the California, Connecticut,**
 25 **Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York,**
 26 **Nevada, Pennsylvania, Ohio, Rhode Island, and Washington**
Subclasses

27 154. Plaintiffs reallege and incorporates all other paragraphs in this Complaint
 28 and further allege:

1 155. Plaintiffs bring this cause of action on behalf of themselves, and all
2 members of the National Class and the California, Connecticut, Hawaii, Illinois,
3 Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode
4 Island, and Washington Subclasses, all of whom are similarly situated consumers.

5 156. Defendant, as sellers of the Products, also made implied warranties
6 including warranting the Products were of the same quality and purity represented on
7 the labels, in advertising, and on Defendant's websites, were fit for the ordinary
8 purpose of the Products and conformed to the promises made on the containers, labels,
9 advertising, and websites that all ingredients were listed, and all warnings given.

10 157. Defendant advertised its Products as safe, when they knew, or should have
11 known, the Products degraded to benzene. Defendant did not list benzene as an
12 ingredient or contaminant anywhere on the Products or advertising. The Products are
13 not of the quality and purity represented by Defendant because the Products degrade to
14 benzene under normal use, handling, and storage conditions.

15 158. Defendant did not tell Plaintiffs or the Class or Subclass members the
16 Products were not fit for their ordinary use because the Products, as advertised and sold
17 by Defendant, degraded to benzene under normal and expected handling, use, and
18 storage.

19 159. Defendant's affirmations that the Products were safe for use were
20 uniformly made to the Plaintiffs and the Class and Subclass members in the Products'
21 advertising, labeling, and packaging, and on Defendant's websites, which were part of
22 the basis of the bargain.

23 160. Plaintiffs, the Class, and Subclass members purchased the Products in
24 reasonable reliance on Defendant's statements, affirmations, and omissions of material
25 health and safety information.

26 161. Defendant's acts and omissions are ongoing and continuing to cause harm.

27 162. Because of Defendant's misconduct, Plaintiffs, on behalf of themselves, the
28 Class, and Subclasses, seek recovery of their actual damages, injunctive relief,

attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are uniform to the Class and Subclasses and the actual damages can be measured and returned to consumers who bought Defendant's Products.

G. UNJUST ENRICHMENT, Individually and on Behalf of the Nationwide Class and on Behalf of the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses

163. Plaintiffs reallege and incorporates all other paragraphs in this Complaint and further alleges:

164. Plaintiffs bring this cause of action on behalf of themselves, and all members of the National Class and the California, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, Missouri, New York, Nevada, Pennsylvania, Ohio, Rhode Island, and Washington Subclasses, all of whom are similarly situated consumers.

165. Defendant has unjustly profited from its deceptive business practices and kept the profits from Plaintiffs and the Class and Subclass members who purchased the Products.

166. Defendant requested and received a measurable economic benefit at the expense of Plaintiffs, the Class, and Subclass members as payment for the Products. Defendant accepted the economic benefits from Plaintiffs, the Class, and Subclass members knowing the economic benefit received was based on deception and omission of material human health and safety information.

167. There is no utility in Defendant's misconduct and Defendant's enrichment from the misconduct is unjust, inequitable, unconscionable, and against the strong public policy to protect consumers against fraud.

168. Because of Defendant's misconduct, Plaintiffs, on behalf of themselves, the Class and Subclass members, and the public seeks recovery of their actual damages, disgorgement of profits, injunctive relief, attorneys' fees, punitive damages, and all other relief allowable under the law. The damages sought are uniform to the Class and

Subclasses and the actual damages can be measured and returned to consumers who bought Defendant's Products.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendant:

169. That the Court determine this action may be maintained as a Class Action under Rule 23(a) and (b)(1), (2) and (3) of the Federal Rules of Civil Procedure;

170. That Defendant's misconduct be adjudged to have violated the state consumer protection laws identified herein;

171. That injunctive and declaratory relief be awarded against Defendant, including but not limited to an order prohibiting Defendant from engaging in the alleged misconduct;

172. That Defendant be ordered to disgorge profits and revenues derived from its course of misconduct and that such unjust enrichment be restored to the class and or distributed cy pres as the Court shall deem just and equitable;

173. That Plaintiffs recover all compensatory damages and other damages sustained by Plaintiffs;

174. That Plaintiffs recover punitive damages as allowed by law;

175. That Plaintiffs recover all statutory damages as allowed by law;

176. That Plaintiffs recover their attorneys' fees and all costs of suit;

177. That Plaintiffs recover all Statutory pre-judgment and post-judgment interest on any amounts; and

178. That all further relief as this Court may deem just and proper be granted.

X. DEMAND FOR JURY TRIAL

179. Demand is made for a jury trial.

///

///

///

///

1 Dated: March 8, 2024

WISNER BAUM LLP

2 By: /s/ R. Brent Wisner

3 R. Brent Wisner, Esq.

rbwisner@wisnerbaum.com

4 11111 Santa Monica Blvd, #1750

Los Angeles, CA 90025

5 Telephone: (310) 207-3233

6 Facsimile: (310) 820-7444

Attorney for Plaintiffs